STATE OF MARYLAND FINAL

Advisory Council on Prescription Drug Monitoring

Kaiser Permanente Columbia Gateway Medical Center

7070 Samuel Morse Drive

Columbia, Maryland 21046

November 6, 2009

9:30 a.m.

Before the Honorable John F. Fader, II, Chairman

Reported by: Kathleen Vetters, CR

ALSO IN ATTENDANCE:

LINDA BETHMAN	DR. J. RAMSAY FARAH
DONALD TAYLOR	NANCY D. ADAMS
BRUCE KOZLOWSKI	DR. IRA KORNBLUTH
DR. MARCIA D. WOLF	DR. ROBERT L. LYLES JR.
DR. NICOLETT MARTIN-DAVIS	JEANETTE QUIGLEY
TONI T. CARTER-RADDEN	JANET GETZEY HART
KAREN THOMPSON	DR. DEVANG H. GANDHI
JOHN J. MOONEY	HENRY S. CLARK III
LARAI FORREST EVERETT	MANDY DAVID
GWENN HERMAN	GAIL AMALIA B. KATZ
MICHAEL J. WAJDA	GEORGETTE P. ZOLTANI
DR. M. GLEN HARPER	ALAN FRIEDMAN
SHIRLEY DEVARIS	PAUL HOLLY
DELORA SANCHEZ	LINDA STAHR
ELLEN KUHN	MARY JOHNSON-ROCHEE
DAVID SHARP	

(Whereupon, the meeting of the Advisory Council commenced at 9:40 a.m.)

JUDGE FADER: First of all I would -- with regard to the minutes of last meeting that were circulated by Georgette, are there any additions, corrections, modifications, criticism more of Georgette?

MR. TAYLOR: I have one, Judge Fader.

JUDGE FADER: Okay.

MR. TAYLOR: On page seven, right at the very top, and I'm sure Linda will back me up. I'm not a judge, so I think it should be Judge Fader and not Judge Taylor on there.

JUDGE FADER: Anything else?

UNKNOWN: Judge, in the transcript it looks like you have taken a vote but there were no numbers associated.

JUDGE FADER: I know. We're going to have those votes. These were just preliminary votes. You're right. Our votes are coming. We've got to implement a procedure for voting and we will have to

talk about that. Okay. Anything else? May I have a motion that they be approved?

DR. FARAH: Yes.

JUDGE FADER: Second?

DR. LYLES: Second.

JUDGE FADER: All in favor?

DR. WOLF: Aye.

JUDGE FADER: Opposed?

(No response.)

JUDGE FADER: I've never been involved in one of these things where anything -- but the last four to six weeks has been the most involved, mind-boggling thing alive. So this is no different. And I doubt that David or Bruce or anyone else has, so.

We have two choices really. One of which is becoming not so viable. And that is we could do another half meeting on the 11th, or we could do an all day meeting on the 4th. I'd much rather do the all day meeting on the 4th and try to buy you a pretty decent lunch. The 11th is Hanukkah. That is not a good day, the first day of Hanukkah.

So I hope that you will all agree that we've got to make the effort possible to be here, probably about between 9:30 and 4:00 on the 4th.

If anybody has any comments or anything about that, I'd sure like to hear from them.

DR. LYLES: When do we have to submit the report?

JUDGE FADER: Michael is going to want -- he has all these people, through the state government, that he has to submit everything to. The report is due 12/31 but, in essence, after that Friday, the 4th, I've really got to get a draft on his desk that Monday that is really going to be 90 percent substantive. All right. Because then he's got to send that off to what, ten people, Michael?

MR. WAJDA: Right here. It goes through the Deputy Secretary, and then up to the Secretary.

JUDGE FADER: But there's all sort of agencies and everybody you've got to send it to?

MR. WAJDA: Correct.

JUDGE FADER: Okay. So I plan now to have

that on his desk, in pretty, hard copy form, with a disk with everything, by that Monday, which is the 7th.

DR. FARAH: Of January?

JUDGE FADER: No, of December. And I don't think Michael can wait any longer for that, that date. As a matter of fact, I think he wants it before that date but he's not going to get it before that date.

DR. FARAH: Judge, is the intent of the report to have what we've been doing, in organized fashion, plus a suggested bill?

JUDGE FADER: No. The legislature made it very clear to me that they don't want a bill. They are very, very covetous, and they always have been, of their ability to put the bill together. You will see missing from their recommendations any statement of a bill. They have a whole process to go through down there once the concepts are in through the committee chair, that they just don't want us peons, or is it we peons, interfering with any of that.

Michael, you agree with that, don't you?

MR. WAJDA: Yes.

JUDGE FADER: Okay. So, I mean, we are putting in here what some other states have done with some other language and the commentary and things like that, but clearly when they ask for a task force, they never want anything.

DR. FARAH: Thank you.

JUDGE FADER: Okay. Yes.

MS. HERMAN: I'm a pain patient so I won't be able to sit through a whole eight-hour day. I just wanted to say that.

JUDGE FADER: Okay. We certainly understand that.

MS. KATZ: I already have airline tickets and I'm leaving in the afternoon.

JUDGE FADER: Okay. Well, as long as anybody can, we'd ask you to stay and see what we can do. The final report that will go will be some things in here, maybe some comments and things like this. The people that are checking on all of this are pretty much checking to make sure that it's in conformity with

state practices and things of that sort.

So if there's a few more comments before it goes on the 31st, nobody's really going to complain about that but it can't be anything real big, substantive. All right? Okay.

The next thing that I want to talk about is today. I would like to start going from now until 11:45 to talk about the recommendations that we put on paper. At 11:45 I'd like to start adding what the additional recommendations will be.

The first I will add, which is the procedure for making sure that the people that submit do submit, and then having immunity provisions for failing to access, and requirements of access, and things of that sort. We do have a compilation material from the various states from that.

So that would be number 11 but then we have to go through and find out what else? Any questions, any comments, anything?

(No response.)

Okay. For drugs included, for the first

draft, I didn't get any comments about any of that. I think it reflects pretty much the unanimous decision -- well, one other vote, and that is that we would not follow those states that do an all-inclusive statutory scheme. You can see the recommendation. It's a recommendation that we do Schedules II and V, plus whatever drugs are added.

Now, in the bill passed in 2006, the legislature specifically struck out impact drugs. So they didn't want this the last time. I think our consensus is that was a mistake and that there should be impact drugs.

MS. KATZ: What are impact drugs?

JUDGE FADER: Impact drugs would be any type of drug that is thought to be of importance in abuse -- abusable -- that contributes to it that would not be scheduled. I don't think there's going to be that many of them, Bob and Ramsay, but there are going to be a few of them. And that's what we said, to leave it up to that. And you can see the comments here.

Now, Mrs. Fader, with her Idaho education

which she claims is far superior, English-wise, than anything here, will be revising all this. I cannot tell her she has no monopoly on understanding things. That would be dangerous for me. Anyone else who wishes to change this language around and things of this sort, add things and correct English, would be very, very much appreciated.

So I'll now ask for any comments on this Drugs to Monitored provision, including the commentary.

(No response.)

JUDGE FADER: We're going to have a lot of commentary on -- most of the other reports, Michael don't have that much commentary?

MR. WAJDA: That's correct. We did a lot of research and looking.

JUDGE FADER: Yeah. We're going to stick our nose in their business and comment to them whether they want it or not with sources and backup and things of that sort. All right? Any question, any comments about this?

(No response.)

JUDGE FADER: Well, I notice that there's a footnote here about Ramsay, Bob, Marcia and Devang. They're supposed to give me some language here to put in on all this stuff. Did you send me anything?

DR. WOLF: I did.

JUDGE FADER: Well, then I must have screwed up and not put it in here. I know I got some comments from you for other things, so I will then be with you on that. But that's just to give examples to the legislature as to what we mean.

Bob, you also gave an example; lowering testosterone or something of that sort?

DR. LYLES: The methadone, yes.

DR. WOLF: I sent that to you with some of the citations.

JUDGE FADER: All right. Well, I am sorry.

DR. WOLF: I'll resend it.

JUDGE FADER: No, wait a minute now. I have a feeling it's in something else here, okay. But I will be with all of you, to rely upon you, for, shall we say, three different examples, if we can get them to

do that. All right? Any comments, any questions on any of this?

(No response.)

JUDGE FADER: All right. Number 2, Linda Bethman.

MS. BETHMAN: For Recommendation Number 3?

JUDGE FADER: Are you 2 or 3?

MS. BETHMAN: I'm 3.

JUDGE FADER: I'm sorry, Linda. Please excuse me. Number 2, the Advisory Council. The Advisory Council was in the 2006 bill. There is an exhibit here showing most people wanting an Advisory Council. I think the consensus of this committee is that you have to have an Advisory Council.

This thing is too fluid. There is too much technology coming up. There's too many people that have their hands in the pie that should, such as DEA, Drug Control, addiction physicians and everything like this. The only people that can keep their fingers on all of this all the time as to what's happening in the marketplace is an Advisory Council. Am I correct in

saying that everybody here pretty much feels that that's the way it should be? Any comments, any questions?

DR. FARAH: Just a few points for clarification. Here you're mentioning the recommendation of an Advisory Council as meeting like three times a year?

JUDGE FADER: That's just because that was in the last legislation. I'm not wedded to anything.

DR. FARAH: Okay. And I feel like if we really need to succeed and we really need to get this on the right track and resolve a lot of these issues, I would recommend that we increase that to six times a year, maybe every other month, because there's a lot of stuff to be done. I want to make sure it's done right.

We can slow down later. But whenever you have start-up we need to be on our toes and make sure that we succeed. A lot of things are going to surface where decision making is going to be done, particularly because we're going to be going for

grants and for money. If we don't do it right, we won't get the money. So we are really tripping on our own two feet.

So I feel that, at least at the beginning, we should put language that the Advisory Council will meet -- I don't know how to word it, but maybe up to six times a year. Or maybe at least five times a year, if you don't want to meet at Christmas or New Year's.

DR. LYLES: I would like to on a monthly basis.

DR. FARAH: Okay. That's even better.

JUDGE FADER: All right. Is that just for the first year until the program starts?

DR. LYLES: Then they can decide.

DR. FARAH: Yeah, then they can modify it. But at least at the onset, there is so much to be done. That's one area on --

(Cell phone interruption.)

DR. FARAH: -- let me turn this thing off.

JUDGE FADER: Okay. Let's just stop there.

Okay. Bruce?

MR. KOZLOWSKI: I was just going to suggest it's easier to say not less than three times a year and then you can set your meeting schedule. Because most groups only meet 11 times anyway. When you get descriptive at the front you tie yourself into something that may not be cost effective in holding meetings for meetings' sake. A lot less language gives you all kinds of fluidness.

DR. FARAH: Okay. Not less than maybe four times a year then, because three would be very --

JUDGE FADER: Now, Ramsay, the boards tell me -- and Linda may know more about this than I do -- but an awful lot of these healthcare boards are telling me they're having an awful lot of trouble getting people to be on the boards and to stick on the boards.

Of course, my position is not -- well, it's not going to be well-received. For instance, for the Board of Pharmacy, I've advocated for years that the way they do things as far as choosing people is a little bit nuts, that each pharmacist that attends a

meeting should be paid $1,000 a day per month for attending. I mean, this is crazy. How can you expect people to give up all this time?

DR. FARAH: The Alcohol Board right now do make that.

JUDGE FADER: And the thing is, if the average physician in the state of Maryland is earning $210,000 a year, what is that per day, and she should be paid that per day for being on the board. But I don't think that Martin is going to take any of those suggestions of mine in this economy. But, I mean, it's crazy to ask people to put in all of this time and not get compensated for it.

MS. BETHMAN: They get $150.

JUDGE FADER: $150? Hell, I drink that much bourbon every day. All right. I mean, seriously, all kidding aside. We have to start rethinking these boards, but I'll be in the nursing home at that time.

DR. WOLF: One of the incentives for reviewing cases is that you get so many hours. You're allowed to earn so many CME hours.

DR. FARAH: It doesn't work. I really studied this. Marcia, I studied this very thoroughly because I wanted it for the Board of Physicians. And after almost 18 months of grueling, it does not work.

The best I could do is to get a waiver of state licensure comparable to so many CME hours and the max you can do is about three hours. So it really is just not worth it.

JUDGE FADER: Any other discussion on this point?

DR. FARAH: $400 a session.

JUDGE FADER: Well, I don't think we're going to put that in that. But, I mean, for the future, people have to start doing stuff. This is just nuts. Any other discussion on this point?

DR. WOLF: Are you talking about the particular point of the payment of the boards?

JUDGE FADER: No. That's just the Fader burr under my saddle. We're talking about the number of meetings.

DR. WOLF: No.

JUDGE FADER: Okay. May I suggest then that we keep it at not less than three, and put a footnote there that it is thought that it's going to have to be much more in the beginning phases. Any discussion on that? Anything, anybody? Can we do that then? All in favor?

DR. LYLES: Right.

DR. FARAH: As an upshoot for that --

JUDGE FADER: Now, just a second now. We're finished with that point. I have to do it the way the fifth grade teachers -- stop, go to the second.

DR. FARAH: No, that's all right. As an upshoot of this advisory board thing, where does it fit to have the review committee --

DR. WOLF: We'll get that later. I've got that right here.

JUDGE FADER: Frankly, this whole bill put a separate review committee in. And that, in my opinion, is going to be one of the things we're going to have to discuss. But separate and apart from the advisory board is a review committee that serves maybe

three, four, five people to the people with the disciplinary board and things of that sort.

DR. FARAH: Right. That's why I was wondering, where does that fit?

DR. WOLF: I've got that for later.

MS. KATZ: It's very common. You know, coming back from that meeting.

DR. WOLF: I actually have questions about the makeup of this particular board. Under (6), where it says four physicians, it says, areas of practice that involve pain management. That doesn't put the onus on the physician to actually have expertise in pain management. It just says that they practice in an area that might involve pain management.

JUDGE FADER: Okay. Well, look. I don't know that much about this and that all -- first of all, when you have a Board of Advisory, there's a number of questions. Number one, how many times a year they are going to meet. Secondly, who is going to be on the board. And thirdly, what is the board going to do? So, Marcia, what do you suggest?

DR. WOLF: I think the wording needs to be tweaked a little bit. You could theoretically have an oncologist that's never written a narcotic prescription qualify under that wording. You also have people on the other end --

JUDGE FADER: -- it can have almost anybody other than a dermatologist.

MS. BETHMAN: Can you take out "areas of practice that involve" and just "with expertise in pain management"?

DR. LYLES: I think you really need to look to your specialty societies.

DR. WOLF: But we can't demand that they --

DR. LYLES: Sure you can.

DR. FARAH: That's what we did. On this Advisory Council we were specific that we should have a representative of the side of addiction medicine.

DR. WOLF: This says, "appointed by the Secretary after consultation with." So then do we change the word consultation to something stronger?

DR. FARAH: I think each position should be

designated. Once you set up what areas, then we should look for that body to recommend somebody to the Secretary.

DR. WOLF: That's what happened now for this go-round. But does this language -- I'm not the lawyer in this group. So is this language significant enough to make that happen?

JUDGE FADER: This language is so ambiguous it can mean anything. I mean, you are correct in your analysis of this language.

Now, here's what I think. It just seems to me that the people that feel strongly about this need to give me some word for an additional commentary to put in here as to what the problems are that could be associated with different wording and different people. And then we ought to see how that works out. Right now it's Marcia and Ramsay. Does anyone else want to weigh in on this as to what the fears are and what suggested language there would be?

DR. LYLES: Sure. This kind of covers it in a way but (6), which is (7) now, four physicians, the

first paragraph under that, "The MedChi, and the Maryland Physician Physical Medicine and Rehabilitation Society, and the Maryland Society of Anesthesiologists With Respect To The Physician Appointments." That seems to draw in the specialty group that I'm concerned about. These are the two groups that really do practically all pain management in the state of Maryland.

DR. FARAH: It's missing the biggest one of all.

DR. WOLF: Substance abuse addiction.

DR. LYLES: Absolutely. We need to add that.

DR. FARAH: That's the whole argument for the mess we have now.

DR. LYLES: And that should be added.

JUDGE FADER: Well, with your permission here's what I would do. I would send out an e-mail to Bob and Marcia and Ramsay and ask for their comments, and anybody wants to have a comment in here on this and -- as to suggested language. And then ask that that be sent to us forthwith so that the next draft

can go out and have some commentary to that effect.

DR. FARAH: Judge, can we add right now the the Maryland Society of Addiction Medicine, because I think waiting for more commentary is just a moot thing. I think we should have it like right now.

JUDGE FADER: All right. Where do you want to put that in there?

DR. FARAH: It says "Substance Abuse and Addiction Treatment appointed by the Secretary after consultation with" -- whichever way you want to put that language is who it's going to be.

DR. LYLES: (7)-(I).

DR. FARAH: Yeah, (7)-(I). The Medical and Chirurgical Faculty of Maryland, The Maryland Society of Addiction Medicine.

JUDGE FADER: Okay.

DR. FARAH: And then the Maryland Physical Medicine and Rehabilitation Society, and the Maryland Society of Anesthesiologists.

MS. KATZ: Is there no society in Maryland of pain specialists?

DR. WOLF: It's a group. It's actually a subsidiary of the Maryland Physical Medicine and Rehabilitation Society, which is incorporated.

MS. KATZ: Okay.

DR. WOLF: And this pain group is a subsidiary of that.

MS. KATZ: Okay. So they would have an opportunity to be appointed through this language?

DR. WOLF: Yes.

JUDGE FADER: Okay. Anything else?

MR. KOZLOWSKI: Considering representation, and especially my administration. I'm thinking through when you're advising a Department Secretary to have someone like me on the Advisory Council, sort of like I'm advising the Secretary when he's going to ask for my advice. That doesn't make much sense. There should be a clear boundary. And I'm not --

JUDGE FADER: I'm not so sure that you're correct politically. No matter how smart John Colmers is, or how much information he has, one of the reasons he's where he is is because he knows he doesn't know

everything, and he needs to ask for advice as to who I should appoint here and there and what should I do. I know he does that.

So I'm not so sure I agree. I thinks he's going to go out and say, who should I appoint here and why should I appoint who I should appoint?

Michael, is that the way most of these Secretaries have operated?

MR. WAJDA: Uh-huh.

JUDGE FADER: You have to be smart enough to know what you don't know.

MR. KOZLOWSKI: Just in terms of my representing -- and not me in particular but representing this here at this. I would like to see some sort of language in terms of if not a member of the board, that you would have certain people from the administration who would be attending the meeting, and make sure that they are there if it is for resource.

JUDGE FADER: Will you send me a footnote to that and I'll float it out?

MR. KOZLOWSKI: Sure.

JUDGE FADER: Okay. Tim?

MR. CLARK: Your Honor, one thing. It may be included in some of the other verbiage here, but I didn't see any references to veterinarians. A couple of the largest cases that I ever worked involved a couple of veterinarians, one of whom was handling more cocaine at the time than Johns Hopkins Hospital and University together were handling. He was diverting it all to the street.

JUDGE FADER: I'm not so sure that vets are going to be on the Board of Advisory Counsel, but pretty soon -- and the next thing Linda is going to bring up is what we should do about vets because I have been amazed at that. Anything else on the Advisory Council?

MS. Devaris: I would like to suggest that either in lieu of, or in addition to the Maryland Nurses Association, that the NPAM be added. The Maryland Nurses Association only has about 1600 members and they represent a broad spectrum, whereas NPAM represents advanced practice nurses in Maryland.

JUDGE FADER: Okay. What is this called? Can you spell that out for me?

MS. Devaris: N-P-A-M. I'm not sure what the initials stand for. I know it's advanced practice nurses in Maryland.

JUDGE FADER: Well, I have to ask you to send me an e-mail on that and put all that here, okay?

DR. WOLF: I think it's the Nurse Practitioner Association of Maryland.

MS. Devaris: That's it. Yes. That's correct.

JUDGE FADER: Okay. All right. And of course that makes sense because a lot of those people who are nurse practitioners are authorized to write scripts and the regular nurses are not. Yes?

MS. DAVID: I would like to add to (7) where is says, four physicians. Maybe if we can be more broad and put mid-level practitioner. Me being a PA writing a lot of narcotics in Baltimore City, I'm somewhat excluded here.

JUDGE FADER: Who are writing a lot of

narcotics?

MS. DAVID: Physician Assistants.

JUDGE FADER: PAs?

DR. WOLF: But your physician is directly responsible for what you do.

MS. DAVID: Right. But I still think that -- I mean, we still have our own license.

DR. WOLF: You do have your own license, but ultimately he's responsible for -- he or she is responsible for whatever you do.

MS. JOHNSON-ROCHE: Does that cover all practitioners?

JUDGE FADER: Well, there's only three separate sources; the PAs, the nurse practitioners, pharmacists, to some extent, all have to sign a contract. What do you call it, Don?

DR. FARAH: Not anymore.

MR. TAYLOR: The protocols, or whatever.

JUDGE FADER: No, there is an agreement.

MS. DAVID: A delegation agreement.

JUDGE FADER: They have to sign an agreement

as to what they can do.

DR. FARAH: Judge, I beg to differ. There is quite a bit of change. We are writing this for 2010 and on.

JUDGE FADER: There's no legislative change. The legislature requires that an agreement be there.

DR. FARAH: The nurse practitioner is independent in her capacity to write narcotic prescriptions, and that's monitored to a certain extent by the Nursing Board. No agreement is there between the physician and the nurse practitioner, or the nurse midwife, as to her prescriptive writing ability.

JUDGE FADER: But there's a difference. The legislature says that she can't write for that unless the Board of Physicians and the Board of Nursing approves it and that she's specifically designated to write prescriptions for that.

DR. FARAH: Uh-uh.

JUDGE FADER: Well, I'm telling you that I know that's what the legislation --

DR. FARAH: It's physician assistants.

JUDGE FADER: Physician assistants and nurse practitioners are both the same. There has to be an agreement.

DR. WOLF: No, they're not.

DR. FARAH: No, Judge. I mean, this is something I've been living with for the last six years and it comes up every month. The legislators said there should be a collaborative --

JUDGE FADER: Collaborative agreement.

DR. FARAH: -- collaborative agreement for nurse practitioners. But collaboration has never been defined in the legislation. They never bothered to detail it.

JUDGE FADER: Okay. Well, I can tell you this way. The courts are going to make fast work of that. A collaborative agreement means that the physician in charge has to designate what that nurse practitioner can do, what that nurse practitioner can prescribe, and that physician is going to be responsible to oversee that.

DR. FARAH: And this has not happened right now today.

DR. WOLF: What about the nurse practitioners that practice independently?

DR. LYLES: They have to have a collaborative agreement still.

JUDGE FADER: They have to have it. You can't practice without a collaborative agreement.

DR. FARAH: But this has never been ruled upon because we --

JUDGE FADER: Well, I can only predict this. The Court of Appeals is going to make short work of that. If you sign a collaborative agreement, that individual has to be certified in those areas through the Board of Nursing, and you are going to be responsible for that.

DR. LYLES: Way back, years ago --

JUDGE FADER: David, do you have something about this? Do you know?

MR. SHARP: I do not. No.

DR. LYLES: Way back, some years ago, 15 years

ago maybe, this went to one of the circuit courts. Collaboration was defined as supervision and that still stands.

JUDGE FADER: Well, then, that was only a little nisi prius judge like me, lower than the belly of the whale that lies at the bottom of the sea.

DR. LYLES: But that was good enough.

JUDGE FADER: When it gets up to the Board of Appeals they are going to say the same thing.

DR. LYLES: No one has contested that and it still stands.

JUDGE FADER: No. I mean -- and frankly, Ramsay -- well, Ramsay, you can shake your head.

DR. FARAH: I have my partner in crime right here. I trust the board, and how many times we've met, how many we've discussed it. We don't really have the teeth --

MS. Devaris: I don't really think we should spend a lot of time on this because I will tell you, as will Dr. Farah, that these collaborative agreements are only like a paper agreement and it's pretty much

independent practice. We don't really enforce them unless there's a terrible problem.

JUDGE FADER: Well, let me make an announcement to the physicians who have signed these agreements. You are responsible. You are going to be responsible. You are going to be held responsible. Your medical insurance policy is going to be held responsible. Because under the practice of medicine these people can't do these things unless they are in supervision by you. And it's going to be a slam-dunk. It's not going to be anything there. But we'll put a little footnote or something in there.

Look, let me tell you how you resolve your problem, both of you. You talk to the Attorney General. You ask for an opinion from the Attorney General. You tell the Attorney General what your problems are and what the situation is. Then you will get an opinion from the Attorney General. Right, Linda?

MS. BETHMAN: Yes, sir.

DR. FARAH: Thank you, Linda.

JUDGE FADER: Well, Linda, do you think that it's a problem?

MS. BETHMAN: Ambiguity is a problem.

JUDGE FADER: I'm predicting there is no ambiguity.

MS. BETHMAN: They're seeing ambiguity is what I'm saying.

JUDGE FADER: They may see ambiguity, but I don't think the Court of Appeals is going to say there is any. Georgette has just told me they can't even get their own CDS license. They're working off of the physicians.

MS. ZOLTANI: We don't give a CDS license unless there's a written agreement and a collaborative agreement for PAs and CRNPs and we check that. So we don't give them CDS licenses. We don't register them unless there is written agreement and collaborative agreement.

JUDGE FADER: Well, I can only say, why is the reluctance, Linda, to write to the Attorney General asking the Attorney General whether there is an

ambiguity?

MS. BETHMAN: I don't know that there is any reluctance. I don't know that there's even been discussion about it.

DR. FARAH: I would recommend that happens.

JUDGE FADER: Okay. Well, I can't write to the Attorney General. The Board of Physicians can. Don, do you have any question about any of this?

MR. TAYLOR: No.

JUDGE FADER: Not really your bailiwick but you have collaborative agreements dealing with --

MS. BETHMAN: Drug therapy management.

JUDGE FADER: Coumadin, warfarin, things of that sort.

MR. TAYLOR: Yeah, drug therapy management. Yes.

DR. FARAH: And, of course, that's a little bit different because the law here is much more clear.

MS. BETHMAN: It's very specific.

DR. FARAH: It's very specific and I don't have any issues at all with that because I'm a member

on that committee.

JUDGE FADER: I most respectfully indicate to you that this law is also clear, and if any physician out there feels that she is not going to be responsible once she signs that contract, she's going to spend $30,000-$40,000 in attorneys' fees defending herself only to find out that she is responsible. That's just my prediction. Am I wrong? Every lawyer in Towson will swear I'm wrong. But we'll put something, a little bit, in there. Anything else with regard to this?

DR. WOLF: We didn't answer the question. Do we need a PA on the committee?

DR. FARAH: It's an advisory committee, for Heaven's sake. There are 21 people already on it.

DR. WOLF: I agree. I mean, I agree with you. I don't think it's necessary.

MS. DAVID: It's not that we need a PA, it's just that I felt like we were excluded.

JUDGE FADER: I can't hear you talking. I'm an old man.

MS. DAVID: Sorry. Sorry, Judge. I just didn't want to be excluded and just put mid-level practitioner. I mean, just because it was just nurse practitioner. Especially since we're considering they were all covered, nurse practitioners and PAs, under the physicians license, then we all should be on there.

JUDGE FADER: Oh, yeah. You're responsible, along with the physician.

DR. WOLF: Should we put some wording in here to acknowledge the fact that we didn't ignore the subject? But should we put some language in here that says that due to the fact the mid-level practitioners are ultimately responsible to a physician, that it's just we didn't think we needed them because of the size of the committee already?

MS. DAVID: That will work.

JUDGE FADER: I can put something in there to that effect.

DR. FARAH: I think it would be that we thought about it.

JUDGE FADER: Okay. But the whole law is geared to making -- you know, as a physician there is Title 14 of the Health Occupations Code that defines the practice of medicine. That is your job description. And there's Title 12 that talks about the pharmacy and the practice of pharmacy. That's my job description. And someone that you delegate under that to do something means you are responsible for that individual, according to your job description.

DR. WOLF: But the relationships have gotten so far out of play, especially at the hospital level.

JUDGE FADER: That may be practical, but that's not going to be legal. Okay. Anything else as far as this is concerned?

MR. FRIEDMAN: Not nursing, but for the panel.

JUDGE FADER: For the panel. Go ahead.

MR. FRIEDMAN: Yes. I sent you a comment regarding the pharmacy composition.

JUDGE FADER: Yeah, here are your comments on page four. Yes. Will you talk about that now?

MR. FRIEDMAN: Yeah. The proposed language

indicates that four pharmacists should be appointed by the Secretary after consultation with the Maryland Pharmacists Association, the Association of Chain Drug Stores, EPIC and any other appropriate organizations; three of whom represent the perspective of independent and chain pharmacies and pharmacists. And Group Model HMO is now defined as of the last legislative session in Maryland Law.

Since we own and operate our own pharmacies and we don't fit under those categories of retail chain or independent, I strongly prefer the wording that says, three of whom represent the perspective of independent, chain and Group Model Health Maintenance pharmacies and pharmacists.

I didn't add it to say a Group Model HMO pharmacist has to be on the panel necessarily. It would be four pharmacists after soliciting advice, but that it represent also Group Model HMO pharmacists. That's all.

JUDGE FADER: Anybody else? Sounds like a good idea to me. How about anybody else? Any

disagreement with that?

MS. BETHMAN: The Group Models would be after -- which association?

MR. FRIEDMAN: No, I would add it to --

DR. FARAH: Number (8) four pharmacists --

MR. FRIEDMAN: (8) Roman numeral I.

MS. BETHMAN: Right. So I guess you would fit in the "any other" organization?

MR. FRIEDMAN: We would be any other organization for giving recommendation and we would fit under -- it's on page four.

DR. WOLF: How many of the Group Model Health Maintenance Organization pharmacy groups are there? I mean, you're one.

DR. FARAH: Medco is one. United Health.

MR. FRIEDMAN: Well, there's HMO, which any health insurance provider could offer as a benefit, like PPO, IPA, HMO. However, to be Group Model HMO, it's going to be Kaiser Permanente the way the definition is structured. It has to do with the Drug Therapy Management bill, specifically.

DR. WOLF: So this really only affects Kaiser?

MR. FRIEDMAN: It does, and our pharmacies in the state. Exactly.

JUDGE FADER: All right. Well, this is going to have to be for a footnote because this is last year's bill. So we're going to put a footnote in here to the effect that this was a matter that was considered and is the reason we recommended change.

Once again, the Attorney General's office for the state of Maryland and the legislature is very covetous of their ability to write legislation and for people not telling them what to do. I would say the chances are they're going to adopt this.

MR. FRIEDMAN: Yeah. We're going to point out that in the mid-Atlantic states we have probably 750 employees and more than half of those -- well, about half of those are probably in Maryland. So a lot of pharmacists are going to be involved in this effort, obviously, in our medical centers. And as we expand, that number is going to increase. Hopefully, we will expand.

JUDGE FADER: Anything else? Everybody agree with that, that we can put that wording in there? Okay. Linda has the buzz saw.

MS. BETHMAN: Alan, your second point. Did you want to talk about that?

MR. FRIEDMAN: Thank you, Linda. In looking at the composition of the panel, and looking at the charge of the panel, that is to reflect advances in technology and best practices in the field of e-prescribing, electronic monitoring.

I wondered if it might be advisable to have a member of the panel who has a background in IT. It could be a physician who has IT experience, or it could be someone else in the healthcare field, or maybe from the state, who has IT experience.

JUDGE FADER: I think the Secretary is going to do that.

MR. FRIEDMAN: Probably so.

JUDGE FADER: And I don't think it's necessary to do that.

DR. WOLF: I agree. Couldn't they just get

what they need from consultation from experts in the field?

MR. TAYLOR: I think that's what is going to happen. If there's a question dealing with IT, I think the committee is going to reach out to somebody with expertise in that field. They're not just going to throw something out. They are going to use consultation with an expert.

DR. LYLES: They will most likely have someone assigned to them.

MR. TAYLOR: They probably will.

DR. FARAH: Where are we?

DR. WOLF: Down at the bottom of page four.

JUDGE FADER: Any other questions, comments?

(No response.)

JUDGE FADER: Okay. Stay away from Linda because tomatoes are going to be thrown.

MS. BETHMAN: I was asked to present Recommendation No. 3 and the issue is who should be the required reporters to input the data into the PDM database? Initially we had talked in our discussions

about "dispensers" and I guess the issue is, who does that encompass?

At the offset it is definitely dispensing pharmacies, outpatient pharmacies and dispensing prescribers. All those prescribers who have what are called dispensing permits. That could be a dentist, it could be a physician. That is basically what the first paragraph says.

The second paragraph starts to get into the exemptions. I saw Marcia's comment about the rationale for the exemptions with respect to institutional pharmacies. I agree with that. Certainly there are -- have been cases of diversion and pilferage in institutional pharmacies.

I did want to clarify, and I had made a note, that it would be in-patient institutional pharmacies. Because, as we know, hospitals have outpatient pharmacies as well. Those pharmacies would be required to report. It's only the inpatient pharmacies. And then, in the examples, there are inpatient hospital, nursing home and hospice.

I was okay with this because the examples of pilferage and diversion were -- from my limited experience, has been staff stealing. That's not going to be captured by the database anyway. It's not -- the kind of conduct or aberrant behavior, I thought, that the PDM program was intended to track was doctor-shopping, that sort of thing. I don't know if that's as much of a risk in inpatient settings. I mean, perhaps some patients jump from bed to bed; I don't know. But that's sort of the scenario I was looking at as the rationale for the exemption of institutional pharmacies. And I'll open it up.

DR. WOLF: What about the Dr. House model? The doctor on TV. He was addicted to hydrocodone and he uses various patients' names and goes to the pharmacy and gets bottles of hydrocodone filled in patients' names.

MS. BETHMAN: Okay. So that's one.

DR. FARAH: I think there's a little bit of difference between acute hospital inpatient where it's a unit dose, where it's going specifically from the

three system: the clerk, the pharmacist, the nurse, the doctor. And it's a completely different story for inpatient.

MS. BETHMAN: Sure.

DR. FARAH: And the whole concept of medication in nursing homes. Because when you are dispensing in nursing homes, if there is a person pilfering, you can see that this one patient is getting a significantly higher amount of dosage that would make sense for his condition.

So I would differentiate nursing home kind of inpatient and stuff like chronic care facilities, nursing home. Because I think the level of expertise and accountability and systems are not as intense, and I personally would have included those.

MS. BETHMAN: The nursing homes?

DR. FARAH: The nursing homes. There's some acute level of care.

DR. WOLF: We already talked about that in the sense that those pills are actually dispensed from a pharmacy, in the patient's name, to the nursing home.

So those would get captured.

DR. FARAH: I just want to make sure that they are. That the exclusion is not written in such a way that --

MR. KOZLOWSKI: Nursing homes use blister packs just like the hospital. The dispensing process in a nursing home is not different than a hospital using blister packs.

MS. BETHMAN: They do use unit dose.

MS. Devaris: That's administering.

MS. BETHMAN: They do the bubble packs -- what are they called?

MR. KOZLOWSKI: Blister packs.

MS. BETHMAN: Blister packs. They are not vials.

MR. GHANDI: But the oversight from the administration is not as close.

MS. BETHMAN: No, you're right.

DR. FARAH: That's the problem.

DR. WOLF: The amounts for Patient A aren't going to be high because if the nurse is stealing

them, then the patient's just not getting their medication.

MS. BETHMAN: They're not going to capture that. It's still an issue of diversion.

DR. COHEN: Right. And you're wondering what to do in terms of that kind of diversion?

MS. BETHMAN: Well, I'm wondering if it's not the type of diversion that would be captured by the database anyway. Why make them report? You know, a patient expires. She only used the first three days of her thirty-day blister pack. The nurse steals the rest. You're not going to know that from the database.

DR. LYLES: You don't return it to the pharmacy?

MR. KOZLOWSKI: That's exactly right.

MS. BETHMAN: A lot of them don't.

MR. TAYLOR: Most of them are not returned.

DR. LYLES: It gets so bad with anesthesiology, that now we have to report a dose-by-dose basis in the hospital. And it's assigned

and charged to the patient.

DR. COHEN: We had an incident that came through where we had a nurse that was actually stealing. What we found out was that the residential program did not have the kind of double checks that they needed so it was very easy to do. Once they were able to do that then you were able to cover. So there are certain things you have to do administratively to make sure that doesn't happen.

MS. BETHMAN: Right. And it's certainly not for my level of expertise, but would reporting requirements to the PDM assist in that regard or not? And if not, then why make the report?

MR. KOZLOWSKI: That's exactly right. There's no reason to do that at this point.

MS. Devaris: The nursing home does not dispense. They don't have pharmacies in nursing homes. I don't know one in this state that does anymore.

MS. BETHMAN: These are nursing home pharmacies that service nursing homes.

MS. Devaris: Right. That's exactly what they do. The medications get delivered by a chain pharmacy service. Very often it provides them with these unit doses. So they're not dispensing. They're administering the medication. There's a big distinction there. And there's no prescription, other than on the patient's chart.

So what we're talking about in nursing homes and inpatient facilities is diversion, stealing, whatever you want to call it. Pilfering. And if we are doing a prescription monitoring, that's not going to pick it up.

DR. WOLF: But one of the things that happens with some of the hospices and the nursing homes is that the requirement for the prescription is actually less.

That's the only place that I can fax a prescription over and that prescription will be filled.

What happens a lot of time is, for instance, somebody that's in assisted living. They'll fill an entire month, or three-month prescription, depending

upon what the patient's pharmacy benefit is. And then they will send that over to somebody within the -- you know, whoever is responsible for dispensing the medication.

I think that data needs to be captured because if they're filling multiple prescriptions from multiple physicians, they're being filled like any other prescription, but the actual requirement for the prescription is less. So I think it's probably a lot easier to forge a prescription.

MS. HART: It's still being dispensed through a pharmacy though. They'll have to report that.

DR. WOLF: Will it be captured?

MR. KOZLOWSKI: It's being captured because it's through a dispensing pharmacy.

DR. WOLF: Okay. Well, then, that's fine.

DR. FARAH: That's fine. We just want to make sure whatever language you write does not exclude that from occurring.

MS. JOHNSON-ROCHE: I think you can distinguish it from the point of dispensing to the

point where it's administered. Because the point it is administered is the end-user point. The prescription monitoring program is not going to capture that. I think it's important to distinguish that in the legislation, because it just won't happen there.

MS. BETHMAN: Well, there is. If you looked at the Virginia, you know, in the commentary. Virginia does have -- and I'm sure a lot of other states have it. There is an exemption for administration, so in the nursing homes where it's administered, in the hospitals where it administered, that's not intended to be captured.

JUDGE FADER: And our charge is prescription drug monitoring, not administering.

MR. KOZLOWSKI: And I'll tell you, having put it in in Virgina for the nursing homes, they are very religious that it's a two-way street. They're tracking to get their money back and do costs maintenance.

MS. BETHMAN: Right.

JUDGE FADER: Don, do you know if there's any nursing homes in the state that have their own single pharmacy?

MR. TAYLOR: To my knowledge there are none.

JUDGE FADER: Okay. Because they have to be issued a specialty license by you because they would not be a full-service pharmacy?

MR. TAYLOR: They would do a waiver.

JUDGE FADER: Right.

MR. TAYLOR: To my knowledge there are none.

MS. BETHMAN: So what was the consensus on the institution?

DR. WOLF: I think it's to the inpatient.

DR. FARAH: Acute hospital inpatient would be exempt.

MS. DAVID: Right. Like IPOP type stuff, right?

DR. FARAH: Right. But not the pharmacy, which is in the hospital that's giving outpatient.

MS. BETHMAN: No, not outpatient. Inpatient, okay?

DR. LYLES: Does this continue to exempt anesthesiology in the OR?

MS. BETHMAN: Yes. That would be inpatient.

DR. LYLES: It's outpatient.

MS. BETHMAN: It's outpatient? But you're administering it.

DR. LYLES: No, we go to the pharmacy. You pick up the drugs for the patient. You administer them. Then you take it back.

DR. WOLF: Are you talking surgery center or hospital?

JUDGE FADER: You're talking about the inpatient surgery pharmacy license.

I had a divorce case once where this physician's assistant was using all this stuff in the emergency room and his wife had photographs of two large trash bags full of all this stuff, over a year, that he had taken -- and the drugs from the operating room. It was unbelievable as to how that could have occurred. That was years ago. I think they've probably tightened up on a lot of that.

DR. FARAH: So emergency room, urgent care, outpatient pharmacies are not exempt? There are a lot of hospitals that have emergency rooms, and that's one provider, one pharmacy, and if we're going to eventually do the 5x5's and the 4x4's.

DR. WOLF: But the quantities are so limited.

MS. Devaris: Not necessarily.

MR. FRIEDMAN: Not always.

MR. GHANDI: ERs are a big source of narcotics and the patients know that, actually. They use ERs quite a bit.

DR. WOLF: For dispensing on the way out the door.

MS. BETHMAN: That's outpatient dispensing, right?

DR. WOLF: No, no. They may give you five pills when you walk out the door.

DR. FARAH: What about the prescriptions they're writing? They are going to fill it outside, right?

DR. WOLF: Yeah, it's captured.

DR. FARAH: So emergency room dispensing is exempt?

MS. BETHMAN: But as long as you're putting it in their mouth while they are sitting in a bed in the ER, that's administering?

DR. WOLF: A lot of times they will put it in their mouth, get their three pills, and walk out the door.

MS. BETHMAN: That's a starter dose?

DR. WOLF: Minimum quantities.

JUDGE FADER: So, Ms. Bethman, what's the language we're going to do?

MS. BETHMAN: Well, so far I have inpatient hospital.

DR. FARAH: Acute.

DR. WOLF: Coma centers are not acute.

MS. BETHMAN: Yeah, I'm worried about acute.

MR. FRIEDMAN: Well, there are rehabilitative hospitals.

DR. FARAH: We have hospice. They're exempt too?

MS. BETHMAN: Yeah, doesn't the same logic apply? Okay. So as far as the nursing home and the hospice, do you want them included? The pharmacies, not the actual facilities. The pharmacies servicing hospice and nursing homes.

DR. WOLF: The ones that are servicing the hospice and nursing homes should be included.

MR. KOZLOWSKI: They have regular pharmacy licenses.

MS. Devaris: They should. They'd be reporting normally anyway.

DR. WOLF: And that's where the difference is. She said the difference between dispensing and administering.

MS. BETHMAN: That happens in a hospital too, you have administering?

DR. WOLF: Right.

MS. BETHMAN: I'm not talking about the facility. I'm talking about the pharmacies dispensing to these facilities.

MR. FRIEDMAN: Right. Like Virginia exempts

dispensing of covered substances to patients in hospices.

DR. DAVIS: But you wouldn't want to cover the dispensing because it would be a double count. Because you've already tracked those drugs through the pharmacy.

MS. BETHMAN: You are covering the dispensing. You're not covering the administration.

DR. DAVIS: Exactly.

MS. BETHMAN: Right, right, right.

MS. Devaris: I would suggest, though, that the first sentence not say outright that there's not -- there have not been problems.

MS. BETHMAN: No, no. You're right, and we're changing that.

MS. Devaris: Yeah, because there have been problems and there are problems.

MR. TAYLOR: Certainly has.

MS. BETHMAN: And I have a revised --

MS. Devaris: You could just say, with prescription drug abuse. That might be a more

accurate statement.

MS. BETHMAN: We're scrapping the whole sentence.

MR. FRIEDMAN: Linda, what about dispensing of covered substances within narcotic maintenance treatment programs?

JUDGE FADER: They're not covered. There are specially regulated by the DEA and the Attorney General. You have to receive a certain permit. And this is the prescription drug monitoring program. The legislature doesn't want us to get our nose in it.

MS. JOHNSON-ROCHE: They have some confidentiality rules that apply.

MS. BETHMAN: Federal. It would be hard to overcome those.

DR. FARAH: They are much more regulated and supervised than anything you could ever imagine. All the diversion studies have shown that's not where the problem is.

JUDGE FADER: No. And the situation is that when I use to put people like that on probation, I

would give them two choices. Either, number one, you go to jail for a long period of time, or number two, you waive your confidentiality to the probation department. And they had a choice.

Now, I think maybe about 400 or 500 of them, guess what they chose? But we specifically had to waive -- to get them to waive those confidentiality provisions so that we could monitor them through the probation department.

MS. BETHMAN: So further down there's also exemptions for samples. I don't think that will be a problem. I did not reference starter doses. Anybody feel a need to reference that as well?

DR. FARAH: Starter doses in what capacity? Reference what?

MS. BETHMAN: Exempting it.

DR. LYLES: Saying that would be Class II.

DR. FARAH: I can't imagine anybody, anymore today, with a Class II having a sample.

MS. BETHMAN: Or a Class III, Class IV, Class V?

DR. WOLF: There's Class IIIs and Class IVs.

MR. TAYLOR: IIIs and IVs are widely used.

MR. FRIEDMAN: Right. But it isn't just Class II that we're worried about. If you're talking about starter doses, it could be Class III, IV or V.

And also, keep in mind, your recommendation earlier on was that the program potentially could expand, and if that's the case, starter dose comes into play. But a starter dose could also be a prescription. A prescription could be written for a starter dose for a patient, so I'm not so sure you want to exempt that.

DR. FARAH: We're talking dispensing here. We're not talking prescription.

DR. WOLF: But you're dispensing a starter dose with a free coupon for ten pills, or seven pills, or six pills. That's a prescription from the pharmacy.

MS. BETHMAN: It is a prescription?

DR. FARAH: That's a prescription. The prescription is there.

DR. WOLF: I don't think it should be excluded, but how do you define it?

MS. CARTER-RADDEN: I don't think you want to exclude it.

MS. BETHMAN: It's defined, I think, under the Pharmacy Act, isn't it?

DR. FARAH: Excuse me. We're talking two things now. What are we talking about? Are we talking dispensing, or are we talking prescribing?

DR. WOLF: We are talking about the language of a starter dose. Dispensing a starter dose.

MS. BETHMAN: Dispensing.

MS. CARTER-RADDEN: But you're not dispensing samples, you're giving a script.

JUDGE FADER: Remember now, that's not a prescription so it's not something that the legislature wants us to get involved in.

Now, we can call attention in a footnote to the fact if these are going to be problems, but the legislature says prescription drug monitoring.

MR. FRIEDMAN: There's a difference between a

sample and a starter dose, and a physician can prescribe a starter dose to be dispensed.

MS. Devaris: Exactly.

MS. BETHMAN: Or a physician can dispense a starter dose.

MR. FRIEDMAN: Absolutely.

MS. BETHMAN: So that's my question. Do you want to capture that or not?

DR. WOLF: How many physicians actually dispense something that's a starter dose that's not a sample?

DR. COHEN: Right. The other part is that doses, even of restricted medications, that's usually not how it happens.

DR. WOLF: Well, the only time I can see it -- I've seen it in acute situation where there's severe migraines or whatever. We'll give the patient a dose right there in the office, either to see how they react to it or to break an acute situation.

DR. FARAH: That's administration. Let's not put a requirement that's going to be a monster.

DR. COHEN: Right. But I always look at these -- these are the outliers, which I think can happen but it's not where the major problem occurs. And, trust me, based upon human nature, something will rear its head and we'll have to deal with it in some other way. But I think that I'd like to keep it specifically to what is being prescribed most of the times, the 90 percent.

MS. BETHMAN: Okay. But, again, we're talking about dispensing.

MR. FRIEDMAN: I have a question. We talked earlier on about physicians. Physicians can prescribe, but there are physicians who are licensed to dispense.

DR. FARAH: 800 of them in Maryland.

JUDGE FADER: Who is their license through, Don, you?

MR. TAYLOR: No, the Board of Physicians.

MS. BETHMAN: Or Board of Dental Examiners.

MR. FRIEDMAN: Right. So the physicians who are licensed to dispense, we're tracking what they're

dispensing because they have record keeping as well. So a starter dose -- I mean, that's part of dispensing in the office. It's not administering it in the office.

JUDGE FADER: No, no. This is caught here, because they have dispensing, right?

MR. FRIEDMAN: Right. I'm saying I don't think it should be exempted.

JUDGE FADER: It's not.

DR. LYLES: Because if you have your own pharmacy in the office, that's not exempted.

DR. WOLF: No, that's not exempted whether you dispense one pill or a hundred.

DR. LYLES: Are you talking about when the salesman drops off samples?

DR. WOLF: Samples are exempted. And the clinical trial supplies need to be exempted, because we don't know what's placebo and what's not. I mean, sometimes we do, but sometimes we don't.

MS. BETHMAN: Well, that was your comment, too.

DR. WOLF: Right.

MS. BETHMAN: Moving on. The other -- what I understand to be a controversial exemption, was veterinarian stuff. You said that's a problematic area.

DR. WOLF: Well, they're exempt if they dispense.

MS. BETHMAN: They all dispense. Most of them dispense.

DR. FARAH: Okay. As long as we can capture.

MS. BETHMAN: So no exemption for vets?

DR. FARAH: No way an exemption for vets. I have a lady who works for me at our methadone clinic, and she gets these pills of 1000 milligrams, which is like 10 times more than a human does, for treatment of her horse. And her access is just like that.

MS. BETHMAN: So the patient is going to be the pet owner? That's who we are tracking?

DR. WOLF: No, you're tracking the vet.

MS. BETHMAN: Right. But one of the data elements is going to be the patient, right?

DR. WOLF: The name of the patient. Is it going to be Fluffy?

MS. BETHMAN: It's going to be the pet owner, right? Is Fluffy doctor shopping?

DR. WOLF: Yeah. But then suppose it's the wife this time and the husband next time and the kid the third time. You're not going -- it's because they do. They will actually dispense Thera-Gesic patches for dogs that have had surgery.

MS. BETHMAN: Absolutely. That's just a thing when you're considering the data elements and the other --

MS. Devaris: It has to be the patient because that's who you are dispensing the prescription to, even though it's an animal.

MS. BETHMAN: But we don't want that data, do we?

DR. WOLF: Yeah, we do. You need that.

MR. TAYLOR: You're tracking the veterinarian, not the patient in most cases.

MS. BETHMAN: We are tracking the vet though?

DR. LYLES: Yeah. In that case you are.

MS. BETHMAN: But the patient also uses their dogs to get the drugs. So you do need to track the patient. The pet owner.

MS. HART: But the pet has to have a problem. So the patient, the human, speaking from someone who spends her life at the vet, the human can't go to the vet and say, oh, my dog is in so much pain. And the vet say, your dog is fine. No, no, really, he's in pain. He needs Vicodin. So the human can't just do that on their own.

MS. BETHMAN: The human can kick the dog and then bring the dog in and say, my dog's in pain.

MR. FRIEDMAN: And, actually, the pharmacy regulations in a number of states do reference, when we're talking about filling prescriptions, they can say for the patient, or the patient's animal. They actually reference that and allow the pharmacies to fill the prescriptions written by the veterinarian.

MS. BETHMAN: Okay. So no exclusion for the vets? We'll have to work out how that data is

submitted later. Interesting.

JUDGE FADER: Now, when they have a dispensing license, I guess they received that license through the Department of Agriculture?

MS. BETHMAN: They'd have to. I don't think they need one. I mean, through the Pharmacy Act they are allowed to dispense for their "bona fide" patients.

JUDGE FADER: Well, how are we going to capture them?

MS. BETHMAN: The bill, I would assume, would capture them.

JUDGE FADER: Well, or would make a recommendation to the Agriculture. All right. Let me look that up and see, because I never thought of that until right now.

MS. HART: Wouldn't they have to have a DEA number anyway to be able to prescribe?

MS. BETHMAN: They do.

MS. HART: Then that's how you would do it.

MS. BETHMAN: I mean, they're licensed

practitioners.

MS. HART: Right. So I think having the DEA number captures them, because you're going to dispense a prescription under their DEA number and it's going to be sent through the database. So I think you've got that.

MS. BETHMAN: Okay. Unless there was any more discussion on that, the third paragraph deals with non-resident pharmacies and these are pharmacies located outside of Maryland. They are either mail-orders or Internet pharmacies, typically. They are licensed to the Maryland Board of Pharmacy as non-residents. The only difference for non-residents is that the way the law exists now, they follow the laws of their home state.

So this would need to be specifically addressed in any sort of bill to say that -- an exemption to that would be they would also need to follow the laws requiring reporting to the Maryland prescription database.

JUDGE FADER: I thought they had to now

anyhow.

MS. BETHMAN: Had to what?

JUDGE FADER: In other words, if there's a pharmacy that's a mail-order in Pennsylvania, they have to be licensed if they are going to send things into the state of Maryland.

MS. BETHMAN: Yes. They are licensed but they have to follow the laws of their home state.

JUDGE FADER: Well, they do. But in addition to the laws of their home state, the non-resident regulations require them to obey the laws of this state.

MS. BETHMAN: No. Except for confidentiality and having a toll-free number where they're accessible 24/7.

JUDGE FADER: Well, then that has to be amended; that's what's you're saying?

MS. BETHMAN: Yes. And if there's a complaint against that pharmacy, the Maryland board has to send it to the home state pharmacy board to investigate.

So that would need to be specifically

addressed that, not withstanding all of that, they would have to report to the Maryland PDM database. You see the rationale there? I don't know if that was a controversial issue or not.

MR. TAYLOR: A lot of other states are requiring that.

MS. BETHMAN: And Internet pharmacies are such a problem anyway.

DR. FARAH: A huge problem, and they should follow the laws of the land here.

DR. WOLF: And most of the states where they're filling these prescriptions, Maryland law is actually more onerous than the state that they are coming from.

DR. FARAH: That's correct. And this is definitely a problem. We know with the benzodiazepines, it's definitely a problem.

MS. BETHMAN: The Board of Pharmacy has had some pretty big Internet pharmacy cases as well.

MS. KATZ: I think we should include them. One of the many things I learned at the meeting in San

Diego is that there are -- the newest thing that is happening among the 40 states that have PDMs, is the development of collaborative agreements among contiguous states. And there's a lot of talk about doing this on the federal level. So it's all kind of cascading, partially for that reason, partially for the obvious reason that people cross state lines.

JUDGE FADER: Now, for those of you that want to know, we already have an opinion of the Attorney General of the United States, and I can't remember which ones, that we cannot regulate pharmacies in other countries.

MS. BETHMAN: Right.

JUDGE FADER: So the Canada problem, to that extent, that's a problem. That has to continue until Canada would sign a treaty with the United States regarding that. I can't remember which Attorney General. Does the DEA remember which one did that? I can't remember. But, anyhow, I know that that's an Attorney General's ruling on that.

DR. WOLF: I mean, you can't mail liquor,

wine, to certain states. Is there any way that you can make a law that says you can't mail from outside the country into the state of Maryland?

JUDGE FADER: No, not unless you sign a treaty with that country. The same as extradition. Linda, how are you doing?

MS. BETHMAN: I think I'm done, unless anybody else --

JUDGE FADER: Well, then, let me ask you all a question. I've certainly been down to the legislature enough over my lifetime to know that they all tell me the same thing. John, if I don't understand something, I'm not going to vote for it.

So the situation is, how much of all of these workings of Maryland law, and these statutes that I put in here for you, should be attached to the commentary? I'm not wed to any of it. I just wanted to put this here for you. We are going to certainly have to make a reference to some of it for where people can go.

DR. LYLES: I think you need to take it down

to a fourth grade level.

DR. WOLF: How about a flow sheet that gets attached to the end that has the different states?

DR. LYLES: It's too complicated.

JUDGE FADER: I'm only talking about these Maryland laws that I've put here. I'm going to keep the snippets from Virginia in place, and I'm adding Vermont, and I'm adding Kentucky.

DR. LYLES: You know, all these guys want something very simple and succinct.

JUDGE FADER: I understand all that.

DR. LYLES: Yes. If we give them too much it's not --

JUDGE FADER: So how about me, instead of putting all this stuff here, Linda and I will work on something that will be a bullet point thing that will refer them to the laws?

DR. LYLES: Absolutely.

DR. FARAH: One other alternative you may want to think of, Judge, is to have an appendix at the end. Because if one of them wants to go through it, they

won't have to worry about digging up the law. Then you do have that in an appendix.

JUDGE FADER: We certainly have a lot of exhibits so I can add statutory exhibits.

DR. FARAH: Yeah, I think that will be a little bit easier if somebody is finicky and wants to go back. They won't have to reinvent the wheel. They can get to it right away.

MS. JOHNSON-ROCHE: I have a question with regard to Maryland pharmacy law. It has to do with when doctors from other states issue prescriptions that are filled in Maryland. Is the prescription monitoring program able to capture that?

MR. FRIEDMAN: Yes, because it will be filled in a Maryland pharmacy.

MS. JOHNSON-ROCHE: Okay. The reason I asked that question is because something I was working on in Virginia where we had a number of physicians issuing prescriptions for the Commonwealth. Virginia's statute requires that if you're going to issue prescriptions in that state, you should be licensed in

Virginia.

We found out that we had a number of doctors sending prescriptions, on a regular basis, through the Internet -- and how does the pharmacy -- I guess it would be the medical board. How does the medical board regard physicians who send prescriptions into Maryland on a regular basis? Are they required to have a Maryland --

JUDGE FADER: If you're a contiguous state and you're close to the border and you have patients from Maryland going there, we don't --

MR. FRIEDMAN: No only that. If you're prescribing in this state, you need to be licensed in the state. However, you give a prescription to a patient, you don't know where the patient is going to take it. If the patient chooses to go to the District of Columbia because they happen to work there, though but they live in Maryland, a DC pharmacy will fill the prescription.

MS. JOHNSON-ROCHE: All right. Well, I guess the question I was asking has to do a lot more with

those Internet prescriptions that come where people consistently order prescriptions. Someone orders prescriptions from a website, say, that's in Portland, Oregon.

MR. FRIEDMAN: Actually, that issue came up yesterday at the DC board meeting, the problem of the Internet. There are mortar and pestle pharmacies that have an Internet composition, so it's an extension of them. But then there are some that have Internet pharmacies that are named different entities, so they are not a licensed pharmacy in the state. There was a whole discussion with the board about, should we consider those non-resident or not, and how to deal with those.

MS. JOHNSON-ROCHE: That's where I was going because it happens a lot.

MS. BETHMAN: Who is filling it?

MR. FRIEDMAN: That's what we said. It doesn't really matter so much where the Internet is, if CVS -- they said, well, CVS -- it's an extension of CVS. And I said, but if it's CVS in DC as the

contact, but it's being filled at CVS-Maryland at the central site, the labeling has to say that, and that pharmacy will need to be a non-resident pharmacy. So it depends on where the prescription's filled as to where it is regulated.

MS. JOHNSON-ROCHE: We had a pharmacy in Virginia that was filling prescriptions from patients nationwide, and they would FedEx them to the patient.

MR. FRIEDMAN: Then they should be a non-resident pharmacy in each state that they mail into.

MS. JOHNSON-ROCHE: But the physicians were located nationwide, as well. This was something that was happening regularly.

MS. BETHMAN: Well, at that point you need to doubt whether the prescriptions are valid.

MS. JOHNSON-ROCHE: It came out in an investigation.

MS. BETHMAN: But the pharmacist needs to doubt.

MS. JOHNSON-ROCHE: That pharmacy is under

major investigation now.

MS. BETHMAN: And that's appropriate.

DR. WOLF: Let's bring it down to a little bit more practicality. Suppose I have a patient that lives in Pennsylvania, works in Maryland, and I go on the Internet to an e-prescribing site to refill a prescription for a patient, or the pharmacy sends me the thing via electronic and I respond back.

(Cell phone interruption.)

DR. WOLF: The patient is my patient. I am a Maryland licensed physician. I'm accessing the computer in Maryland, but everything may be happening in Pennsylvania.

MS. JOHNSON-ROCHE: That's perfectly legitimate. What we try to do is capture instances where it is not legitimate.

DR. FARAH: But this example may not be a very good one because Pennsylvania is a contiguous state. You wouldn't have that problem with West Virginia, Virginia, Maryland and DC.

DR. WOLF: Okay. Suppose it's a snowbird and

they go to Florida?

MS. JOHNSON-ROCHE: I mean, if it happens where they take their prescriptions back up in Maryland and Washington, DC, is that going to raise our attention?

MS. BETHMAN: You're usually looking at volume and the same drug.

DR. DAVIS: I don't know. You can't e-prescribe a controlled substance prescription anyway.

DR. WOLF: No, you can't.

DR. FARAH: Not at this time but it's coming.

DR. WOLF: But I can mail my patient the prescription in Florida.

JUDGE FADER: Let me ask you a question. Can't you e-prescribe III, IV and V?

MS. BETHMAN: No.

JUDGE FADER: You can't e-prescribe anything? Okay.

DR. WOLF: Not now, but apparently the trend is going to be coming.

JUDGE FADER: I know that there's a regulation to come up though.

MS. Devaris: I think it's stuck in your hierarchy or whatever.

DR. FARAH: It's happening within the next three years.

JUDGE FADER: Ms. Bethman?

MS. BETHMAN: I can send out a revised one based on our discussions today.

JUDGE FADER: Send it to Georgette and myself, and then let me stop over and sit down and talk to you about some of these things.

MS. BETHMAN: Okay. All right.

JUDGE FADER: Anything else with regard to that? Here's your comments. Here's Marcia's. Anything else anybody wants to say that we didn't cover?

MS. SANCHEZ: I made a comment and if there's any questions, I can address them, but otherwise I'm very happy with the Council.

JUDGE FADER: All right. How about Mike

Souranis' comments?

MS. SANCHEZ: I mean, I can't comment on his comment. I will anyway, but I mean, if anyone has any questions for my particular comment that I made, that's fine.

JUDGE FADER: Okay. Anybody have any comments? Any questions to ask? Anything?

(No response.)

JUDGE FADER: Here's the rest of your comments. Bob Lyles?

DR. LYLES: I'm okay. I'm satisfied.

JUDGE FADER: Let me just give everybody an opportunity for a few minutes to go through all those things and see if you have anything to add.

(Short break taken.)

JUDGE FADER: Ms. Bethman, will you call and see if anybody has any comments on the comments?

MS. BETHMAN: Anybody have any comments on the comments? Are we finished with Recommendation No. 3?

MS. SANCHEZ: Yes.

MS. BETHMAN: It's unanimous.

JUDGE FADER: Okay. Now, with regard to these comments, there will be a note about comments sent in. And although I'm going to ask people to contract some of these for space reasons, anybody that had made a comment, we'll have that comment, the date made, and your name. Anyone who wants to say I subscribe to this and I agree to this should do that, and that will be added on. Okay?

Data information to be submitted. Now, the previous legislative enactment was very specific as to the information. Ours is going to say, please don't do that. And it's going to argue to them that the technological information that has become available, the fact that we are dealing with some databases that have been developed over the past 20 years, some of which somebody said is archaic but I'm going to try to use another word that's different than archaic but says the same thing, is to the effect that we would ask this legislature to take a look at what some other states have done through regulations and things like this, but to leave the final decision to the Advisory

Committee.

Any comments, any questions about any of this? Have I adequately reflected the sense of this Advisory Council? Does anybody think the legislature should be specific or whatever?

DR. WOLF: The only thing that I would add in looking at what's under Recommendation No. 4, as far as the data, is that it needs to be made clear that it's not just the substance but minimum does too. That's the only thing that was left out. It has the covered substance and then it jumps to quantity, but it doesn't actually say the dosage.

JUDGE FADER: We'll put a footnote in there to that effect. I'm not sure it went past me but, boy, that's a big consideration.

DR. LYLES: Marcia, if you look at what some of the other states are doing, and also what's available, the prescriber's name, professional address, telephone number, fax number, federal DEA number, state DEA number, prescription number, medication number, strength of medication, amount

prescribed, date of prescription. It goes on and on with some of the data that's being submitted.

DR. WOLF: I think that's overkill.

JUDGE FADER: All right. Now --

MR. KOZLOWSKI: If I can ask a question?

JUDGE FADER: Bruce, can I ask you a question first?

MR. KOZLOWSKI: Yes, sir.

JUDGE FADER: You notice that I have incorporated your comments in a couple of these things. Are you going to update that October 1st report, or is that your report?

MR. KOZLOWSKI: We've done an annotation to that and sent it to Georgette. We brought the language down about 40,000 feet and we condensed it a bit.

JUDGE FADER: All right. Well, somewhere along the line I need whatever final you're going to do.

MR. KOZLOWSKI: Okay. That's no problem.

JUDGE FADER: On, or about, November 30th.

MR. KOZLOWSKI: All right. We'll have it earlier than that because it's already sitting here.

JUDGE FADER: Okay. And to the effect that that's the one you will make reference to for your comments, is that doable?

MR. KOZLOWSKI: Absolutely.

JUDGE FADER: Now, then, I will have to get a real clean copy from you to attach as an exhibit.

MR. KOZLOWSKI: Sure.

JUDGE FADER: All right. Now, you had a question?

MR. KOZLOWSKI: Yes. It was a question in the context of the six items in there for information. I'm kind of at a loss as to why diagnosis, primary diagnosis, is not there. Because when you do a look-see in the context of a particular incident, you can tell an awful lot if the diagnoses and the particular drug that's been prescribed are somewhat out of sync. There's even software to do that. There has been for years.

DR. WOLF: It's a royal pain in the neck.

MS. SANCHEZ: Pharmacists don't have diagnosis.

MS. BETHMAN: It's not on the prescription.

DR. WOLF: Yeah. For me to have to put it on each and every single prescription -- and you're talking to what happens if it's off by a digit, or it's a non-specific code, it's a nightmare.

MR. KOZLOWSKI: All right.

MR. SHARP: I have a question. Just for clarification, are these data elements -- was the consensus that this would be determined by the Advisory Council, or is this going to be in statute, a regulatory statute?

JUDGE FADER: The 2006 statute had it in there. Our discussion from here is, things are changing. It's going to depend upon what type of database we go for. There are so many things out here that it's better to leave, through regulation, to be adopted on recommendation by the Advisory Council. Now, does anyone object to that? Does anyone feel it should be in the statute? Then we need to know.

DR. FARAH: The dose thing. I don't know how fast it's going to be but if you're going to do it, I mean, the dose is very critical. I mean, that's what it is all about, actually. Because quantity is just not sufficient.

DR. WOLF: I think it was intended to be in there and was just inadvertently left under the covered substance.

DR. FARAH: Maybe under (4), quantity and dose.

DR. LYLES: That's done by the Advisory Committee.

JUDGE FADER: Let me call your attention to something. I meant to say, to be determined through regulation, not the Secretary. Because this is something that really needs to be in a regulation, and I did not see that I messed up on that until right now.

May I, therefore, suggest to you that this is something that needs to be by regulation that everyone can see. And if anybody has a comment on that, let me

know.

MR. KOZLOWSKI: Wouldn't operatively the Secretary be doing it through regulation anyway?

JUDGE FADER: I have no idea how Maryland State government works, but it just seems --

MR. KOZLOWSKI: That's the only way it could be done. Whatever decision he makes would have to be put through the public comment, the regulatory process.

JUDGE FADER: Well, he's going to make decisions with regard to impact drugs and things like that.

MR. WAJDA: It's needs to be in the statute that you want it in regulation, right?

DR. FARAH: Exactly.

MR. KOZLOWSKI: Is that right? Okay.

DR. LYLES: You mean specifics needs to be in the statute?

MS. BETHMAN: No. They want a regulation in the statute.

MS. KATZ: It also gives some fluidity to it

if there are needs. For instance, if we were to enter into a collaborative agreement with the adjoining states, and they had some data element that we did not and that precluded the collaboration, that would give us the opportunity to say, yes, we see the point.

JUDGE FADER: It's also the politics of this, because I don't think there's any way that the legislature would ever approve letting the Secretary do this without it being part and parcel of the regulations. Any other questions, comments?

MS. KUHN: I just don't understand what a prescriber's identifier number is, and is that the same thing as a DEA number?

DR. FARAH: Each prescriber now has to have a national number.

DR. WOLF: NPI number.

JUDGE FADER: National Provider Identification Number.

MS. JOHNSON-ROCHE: I have a question about that. That number has to do with payment. It's the third-party payment? That's the purpose of it?

DR. FARAH: That number is an EIM number, which has tax certification, which is different than a prescriber identification number. It came out from Medicare.

MS. JOHNSON-ROCHE: It's just to enable third-party payment? I think more appropriate might be the DEA number, because they can't be without that number. The other number really is irrelevant to the dispensing.

DR. WOLF: It was actually implemented so that Medicare stopped paying dead physicians.

DR. LYLES: The NPI number is not necessary to practice medicine.

MS. SANCHEZ: But the DEA number is mandated to fill the prescription.

DR. FARAH: But that's strictly required from 224.

MS. JOHNSON-ROCHE: So why don't we have that as a part of the prescription monitoring program?

MS. EVERETT: I guess I was wondering, too, because of the veterinarian thing you were talking

about earlier. They would not -- I don't know. I'm guessing they do not have an EIM number?

DR. FARAH: I have a question then. What if at some point you go beyond the scheduled drugs, then the DEA number would not apply anymore, right? And so you are going to be asking these people --

MS. BETHMAN: Does the NPI number apply at all to this?

DR. WOLF: What about the state license number?

MS. ZOLTANI: Before they get a DEA in Maryland they have to have a CDS number. If they don't have a CDS number, Controlled Dangerous Substance registration number, then DEA will not give them a DEA number.

MS. BETHMAN: But the NPI seems useless.

DR. LYLES: The NPI is useless for this.

DR. FARAH: The nurse practitioner has it.

DR. WOLF: The veterinarian doesn't have an NPI number.

DR. FARAH: The physical therapists have it.

DR. LYLES: The NPI number is not something you want to use for this.

MS. ZOLTANI: No. It's mostly for insurance purposes.

DR. LYLES: The only reason you have an NPI number is for billing.

MS. JOHNSON-ROCHE: So the DEA is for other states coming in?

MS. ZOLTANI: Exactly.

MR. FRIEDMAN: But if you're going to expand this eventually for all drugs, and let's say you have a physician or nurse practitioner that's choosing not to prescribe controlled drugs. They would not need to get a DEA number, but they would have an NPI number.

DR. WOLF: Don't you need a DEA number to --

DR. FARAH: No. Only 225s. Only that. And so if you are looking at impact drugs down the line, then you will have to force them to get a DEA number. Then they would have to.

JUDGE FADER: And of course, can I point out that --

MS. JOHNSON-ROCHE: You know, something else that comes up is if the doctor or, say, anybody has more than one location they are operating from, if they're physically -- they have two separate DEA numbers. For me, I think it captures across the board on this.

MS. ZOLTANI: And they need a separate CDS number.

JUDGE FADER: Isn't this another good reason why the Advisory Board needs to jump in on this?

MS. BETHMAN: Remember, because if you are going to include Internet pharmacies, the doctors are probably going to be out of state. Not all states have CDS numbers, so you wouldn't be able to do that.

MS. EVERETT: But they all have DEA numbers.

MS. BETHMAN: Well, unless you're not doing a CDS.

MS. ZOLTANI: The license number won't work because it will be a formatting issue.

DR. LYLES: You can do digestible formatting. It's not a problem.

DR. FARAH: I have a question. The DEA, for the location, is it individually attached or is it the center? Like if you have --

MR. FRIEDMAN: If you are a prescriber in Maryland, you need a DEA number. If you also prescribe in Virginia, you need a separate DEA number.

DR. FARAH: If I have a surgery center in Baltimore and I practice in Hagerstown --

MS. JOHNSON-ROCHE: The person that physically handles the dispensing, does that require a separate DEA number?

MR. TAYLOR: It's location specific.

DR. WOLF: Per location. It's specific to the location. Nobody else in that location can use it, no. It's your number at that location.

MR. GHANDI: The one at the vet that doesn't have a DEA number is trainees, and they prescribe quite a bit.

MR. FRIEDMAN: They use the hospital number.

MS. JOHNSON-ROCHE: They're using the hospital number?

DR. WOLF: Yes.

MR. GHANDI: That will not be captured.

DR. WOLF: But their name might be printed on the prescription. I mean, the hospital's name is printed on the prescription. They may print their name at the bottom so you can see who the prescriber is, but the trainee, their name is not even printed on the prescription.

DR. LYLES: So are we going to go to the Advisory Committee, and the Advisory Committee will file the regulations?

JUDGE FADER: This is another good reason why it should be through regulation upon the advice of the Advisory Committee, because there are so many things right here that so many of us didn't know.

DR. DAVIS: So are we going to make a recommendation that the NPI number is not --

JUDGE FADER: No. We're going to make a recommendation that the Advisory Board, not that they decided but that it be implemented through regulation upon consultation with the Advisory Board. This would

have to be through regulation.

DR. DAVIS: These criteria?

JUDGE FADER: The criteria as to what's in there. Anything else?

DR. COHEN: No.

DR. FARAH: Are you going to make a recommendation on this for the DEA number, in addition to --

JUDGE FADER: Well, the thing is, I've tried to record all of the comments as additional evidence as to why this should be on regulation that is passed by the Department of Health and Mental Hygiene, upon recommendation by the Advisory Board.

We're all sitting around here talking about things -- I can look at your eyes -- some of you never thought about, some of you never knew about. And that would all be brought to the attention of the Secretary for the enactment of a regulation.

I recommend, or suggest, that our recommendation is that the Advisory Board determine what data is to be submitted, or advise and it be

implemented through a regulation. as opposed to being in the statute.

DR. FARAH: Yes. And could we, maybe, because it's a charge we're expecting to do, put a pointer of some of these reminders that we have spent so much time coming up with for the next meeting?

JUDGE FADER: Well, I've tried to write down as much as I can. I'm going to send it out and then try to ask for comments so that we can include it as greater evidence as to why we feel that this is not something that should be in the statute.

Okay. Well, there's always emergency regulations, things of that sort, too, if we need to.

How submission of data information is to be made? Bob Lyles, David Sharp, Bruce Kozlowski. Bob Lyles is the point person.

MR. KOZLOWSKI: Also our boss, by the way.

DR. LYLES: Yeah. Dave, do you want to go through your development?

MR. SHARP: Okay.

DR. LYLES: And I'll fill in, okay?

MR. SHARP: All right. So I think really the question that's posed is one that's been on the table since I've been helping out on this Advisory Council for more than, I guess, six months.

And that is, really, there are two ways to do this logically. You can have the traditional stand-alone client server model that sits somewhere that's domicile, and owned by someone who maintains it, who controls it, who keeps the watchful eye out under it, and allows the information to be added to it, and who grants access to the individuals who are approved, in this case, by an Advisory Board or via reg.

That model is the model that is currently in play nationally. It has been the model that's been in existence for more than 15 years.

JUDGE FADER: When you say nationally, you mean other states?

MR. FRIEDMAN: Other states.

JUDGE FADER: There's no national model yet?

MR. SHARP: There's no national model and

that's where I'll take you. So this model has been a very effective model, this client server model, if you will. But it worked in an environment where that was all the technology that existed. It's the wonderful VCR, and then along comes DVD. All of a sudden that VCR technology is not maintained as well, and it becomes a bit more obsolete.

JUDGE FADER: I understand what the stand-alone is, but I honestly don't understand the DVD and why that's different.

MR. SHARP: I'm going to get you there. So the technology that we're talking about in the stand-alone model has been effective. It worked. But it doesn't allow for a lot of modification, so we're just talking about data content, if you will. It doesn't allow for forward thinking.

Let's say we were talking about a veterinarian a few minutes ago. It doesn't allow for change very readily because it's a very tight, boxed system, if you will.

As states have begun -- and the national focus

has been on moving forward about health information exchange. That is a concept. A new system has emerged, a new model of information gathering, if you will, a new model of data sharing. That model is essentially viewed as more of a distributive model. Let me tell you what that is.

That's where the end-points, the physicians, the pharmacies, the hospitals, anybody who is a prescriber in the system in which they maintain patient information, the information is stored there and in this virtual network, the Internet, if you will.

Upon requests from either a physician or from -- it could be law enforcement -- and providing they are approved again by an advisory board. It reaches in to this distributed model, this network, and pulls out the information in question and builds it in a format which you request. It's very fluid. It can change.

As the rules changed, the Advisory Board defined new rules. The rules of the system can change

very quickly. The information is also in near realtime. From the point of which a pharmacist would fill the prescription, you can have access to that within minutes versus in the current system that's in play in a lot of states. It's not realtime. It becomes realtime, or available, once it's keyed into a system.

The pharmacist then sends the data on some sort of medium, to wherever it needs to go. And then an analyst loads it into another computer. So availability can be a week, it can be a month, or it can be not at all.

This opportunity allows for you to have real time access to 100 percent of the information that goes through, whether it's a cash transaction or whether it's a transaction covered through an insurance company.

JUDGE FADER: And every state that talked to us at the Washington meeting indicated that they are trying as fast as possible to move to realtime.

MR. SHARP: Yes. The model that I just shared

with you is where Maryland is going for health information exchange anyway. This model is already being developed. I think most go people, well, when is that model fully functional and available? Because its technology -- it's being developed on a service basis, so today the technology is being built to handle medication delivery to the requester.

The information for a prescription drug monitoring program would be a service that we build. So if the legislature next year said, we want this handled through the statewide health information exchange, it would then have to be built. The use case is really the architecture. It would be designed and built in. The journey is about three years to build it.

But, likewise, just as I gave the example of the VCR, the client server model, just as the VCR is becoming obsolete, is exactly what is happening to these stand-alone systems. They are becoming obsolete. They are not getting maintained. They are not getting the technology support from the software

vendors who own these systems, because they are not inspired to. There's no value in it. These technology vendors are moving in directions where they can get ROI on whatever products they develop.

JUDGE FADER: ROI?

MR. SHARP: Return on investment.

JUDGE FADER: Return on investment. Okay. Just remember who you're dealing with.

MR. SHARP: So just real quick, let me just sort of finish the picture before your questions. The model, as it becomes obsolete, if the state opts to do that, it's going to take the state about three years to implement a model that's inevitably going to be obsolete on the heels of being implemented.

So if that's the decision that's being made, the lifelong existence of this system is very small. By the time all this hard, wonderful, good work is done and the legislature passes the bill, and the pharmacists spend all this money to buy this software, to then have to create a dual system and bring in staff, potentially to maintain it, or hire

consultants, the other system, the HIE, the statewide health information exchange, will already be functional.

So it would be more logical to have built it in as a service, where there's not an additional burden of financial costs to the pharmacist, or to the physician.

JUDGE FADER: All right. Now, let me ask you a few questions. How much can we rely upon your three-year projection? And, David, I'm not trying to be -- I'm trying to be a lawyer, the devil's advocate. How much reliability can we place on that three-year? Certainly some legislator is going to ask that.

MR. SHARP: I would answer this way, Judge. The three-year clock starts when the approval in the funding mechanism starts for the statewide HIE to build it. So if it takes the state two years, through a legislative process, to get this approved, then it's three years from the time it's approved.

JUDGE FADER: Then it's not approved yet?

MR. SHARP: Right. So if it's approved in two

years because the bill grows and changes in the laws, and it takes two sessions, it's still a three-year journey, minimal.

JUDGE FADER: But one of the considerations -- and here's the point, is that we're going to be able -- as Michael is going to tell us and you're going to tell us soon -- to get money from other programs to start this, all right? But they are only going to fund toward a stand-alone program probably as it exists now, and not allow us to use that money toward the contribution of your program, or am I incorrect about that? I just don't know the answers one way or the another.

DR. LYLES: Let me answer that. I think you are incorrect about that. If you look at the statewide health information exchange, and the PDM would be a subroutine of that, you pinch off the data you want. You're not going to pinch the entire health information exchange. The data elements are going to be -- correct me if I'm wrong -- are already going to be there. It's a matter of reaching in and

developing --

JUDGE FADER: Bob, how can you start it until they start their main base?

DR. LYLES: Because you don't define the source of the data. The pinch off is a stand-alone system.

DR. WOLF: You define the delivery of the data, not where the data comes from.

DR. LYLES: It's just a matter of how you put the words together. Go ahead, Dave.

MR. SHARP: So I think what you also find, because as Dr. Lyles was mentioning, and others, the data is there today anyway. So what we're really proposing is the highway, in the middle, that allows these technologies that already exists all over the place.

JUDGE FADER: Not only is the data there, but it's being utilized every day in the state of Maryland through so many other third-party people that are processing all of that information.

MR. SHARP: And what you do get, that we've

talked about in the past but haven't talked about a lot recently, is the security protections that we've seen come to question in Virginia and other states where the security protections that are afforded a statewide HIE are far greater than what's in an existing stand-alone system. You can't build a stand-alone system and give it the same protection. It's not technologically possible.

JUDGE FADER: Suppose the legislature says to us now, you know, there's really a lot of pressure on us getting to this, so can't we use some of this money to develop part of the system for the pharmacy program, and then that would click in to work and be a part of your health information exchange? What's the answer to that?

MR. SHARP: If I hear your question correctly, today we have a couple of things going on with funding. The Maryland Health Care Commission and the Health Services Cost Review Commission have funded $10 million to put this thing in motion.

We've recently applied for, under the ARRA,

the American Recovery and Reinvestment Act, the federal government stimulus package, for two grants. One of them has a maximum of 9.3 million, and the other has an 8.5 million.

We won't know until December if we are eligible for any of that money. Could some of that money be used to build this as a use case? The answer is yes. But it wouldn't be if the legislator goes, well, we don't like this. We want it to be a stand-alone system.

So if there is some insight, and say this group has clearly -- that's the recommendation. The statewide HIE could begin to look at that as a used case anticipating what might come down in the future. Now, we wouldn't build it because it wouldn't make sense. The legislature, at the end of April, could go, nope, we've changed our mind.

JUDGE FADER: Yeah. You'd have to get your authorization.

MR. SHARP: Yes.

JUDGE FADER: Okay. But, I mean, I would be

surprised if one of the legislators, or two, didn't say, look, we really -- let's tell you, don't want to wait on this, but at the same time we don't want to over duplicate or have a problem with later corresponding with your system. So what can we do about that?

We have funding available now. We can get funding through Rogers and other things to invent the system. What can we do to do this now? What did Oklahoma say? It took about nine months to a year from the time they started to get it up and available. Vermont pretty much said the same thing.

So that we don't interfere and we meld your system, what is your answer going to be to that?

MR. SHARP: It's always the same. It's funding. If additional funding is added to this, it can easily be added. It can easily be built today. But, right now, it's a question of funding.

The $10 million that was allocated was for specific sets of services. The state said, we're buying, for $10 million, this list of services.

And that's what the $10 million is being used for.

JUDGE FADER: Well, I expect that you and the Commission are going to go down to the legislature -- and I'm saying this with all good kindness and expectation --

We want our funding because we want to start on this and we believe that the best way to go is to wait for it. Okay? And that, in my opinion, is what you should do because you're a separate agency of government that should say this.

The legislature is going to say to us, well, we don't want to wait that long. We want to start this right now. We want to show the citizens we're doing something right now. We want to get DEA off of our back, who is all the time saying we should do this, we should do that. We are forty states, et cetera.

MR. SHARP: My response to that, Judge, is you have the race between -- sort of like in my mind -- the rabbit and the turtle. You click and say, go and see which -- if you said we want to implement the

stand-alone system because that's how we can convince the consumers, sort of in a false way, then there's something in play.

By the time it gets to the finish line, you know, it's the jackrabbit. It crosses first. Then in comes the turtle, the slow moving thing. The turtle keeps on going because the stand-alone system is exhausted and won't support it.

JUDGE FADER: All right. We are going to have to have two options for the legislature, because they are going to insist upon that.

MR. SHARP: Okay.

JUDGE FADER: And it will be up to the legislature to decide what to do, and rational sometimes is not --

MR. SHARP: I see.

JUDGE FADER: Okay. You can't say that publicly. I can.

DR. FARAH: I would like to recommend the roadrunner, neither the turtle nor the hare. The roadrunner would be to hire a vendor which we can,

with the language that we need, set it up in such a way that we move over to that once you're up and ready.

MR. SHARP: It won't work.

MR. KOZLOWSKI: It won't transition.

MR. SHARP: You can't. You can't bring in a vendor. What happens when you bring in a vendor is you lose neutrality of technology. The vendor will hold you hostage for this product until kingdom come.

So if the state decides it has a deep pocket, and continues funding this through the vendor, even though you can contractually say, we expect the transition by -- it will not work. It sounds good, but it will not work.

It sounds good, but it won't work. That's the whole idea of not having a single technology platform to build these things on. And vendors are only pushing the technology platform.

DR. LYLES: Let me give you an idea of what they are dealing with. As you see in this, 47 acute care hospitals, 8,000 physician practices, 1600

pharmacies. We're dealing with 65 pharmacy benefit managers that represent 91 percent of the market share, with the big ones being Medco, Express Scripts, CVS, Caremark.

We're looking nationwide at 3 billion prescriptions a year. So you've got a fair amount of data that you are going to deal with here. We're only going to look at two through five. I don't know what percentage of that is two through five. The provider databases have to be compatible.

If you look at EMRs, electronic health records from hospitals, paper, and you distill that into what has been developed through the pharmacy groups and Surescripts, that's their -- they provide access to about 99 percent of the pharmacies now throughout the U.S.

The pharmacist database -- I've tried to get information on it. But there are over 200 pharmacy software vendors that have distinct databases. What this whole effort toward the State Health Information Exchange is, is that you bring together that data into

-- from a distributive point of view into one access area.

If you look at e-prescribing, they are connected to everybody. The pharmacy data submission, we've talked about that.

Electronic Internet, fax and paper: The safest seems to be now. You've got a flat database, two-dimensional database. You call the database. They fax you the information you need. That's unequivocally safe, for the most part. But we're advancing now into security efforts, with audits and all this with the Health Information Exchange, that a small vendor is not going to be able to accomplish in the future.

The provider database extension: Same thing. We've got electronic e-prescribing right now. We're just working on this. It's in its infancy. We probably have less than a third of the physicians in the state of Maryland actually doing it.

The database architecture: You've got several pages of this here.

Distributed database: This is something new to most of you. But it's where the future of all this is going to be, especially with the federal government putting in billions of dollars with this.

The comments I had to Dave was that we need realtime access, and we also need interoperability requirements. The interoperability requirement is going to be the foundation of all of this. It's got to be compatible with each other, such that the data can flow back and forth. You're going to have to have that hub here to do that.

Some of the other comments I had is that the database should be considered a health record. And that is something we haven't talked about yet. As defined in Maryland -- and it needs to comply with Maryland regulations. What they are going to develop and we pinch off, with nothing else, will comply with state of Maryland regulations and statutes for IT and so forth, including the regulations that are going to be promulgated through House Bill 706.

Now, House Bill 706 will provide an avenue for

pharmacists and physician providers to be compensated for actually using the database. And that's all in the works.

So what we're running into now is not the bill we had in 2005, but we're running into a whole different scenario; that technology has changed us so much. It's like going from a black and white TV to flat screen to your computer.

MR. KOZLOWSKI: Or analogue to digital.

DR. LYLES: Analogue to digital, yes.

DR. FARAH: I understand this. But I can tell you, thinking that nothing is going to happen for three years is not a goal.

JUDGE FADER: I can only tell you this, Ramsay. I don't know whether that's so or not, but I do know that if we have to go to the legislature and say, here is Dave Sharp and Bruce Kozlowski. They are going to have a view, and they're going to tell you to wait, and they are going to tell you the reasons that you should wait.

Now, if you want to wait, fine. If you don't

want to wait, here's the other stuff that we can do for you through an independent vendor, here's the funding, here's the stuff that's going to come from here. And then you make the decision. Okay?

Because this is not our decision to make. This is a political decision. I can predict one thing. They are not going to do anything during the 2010 legislature because there is no money to do anything, all right?

If I would go to Mike Miller and say, Mike, this is going to cost you $1.50, he is going to say, the hell with you, John, I don't want to hear it. So it's not going to go anywhere, but we've got to tell them about the two options.

DR. FARAH: But if I can get that 500 from Rogers then we can get started.

JUDGE FADER: That's up to you to go down and you'll be there en masse and telling the legislature and all of this stuff too. I would like to see what Mary has to say.

MS. KATZ: Can I make one comment about the

implementation grant? It's essential, in terms of this grant that will be available next year for $400,000, that it be written into the law, and that there be a submittal number. So whoever is writing that grant has to be able to refer to the fact that Maryland is in the process of considering -- or has passed some sort of a PDM statute. And then -- it's a circle. The law has to reference the grant, and the grant has to reference the statute.

JUDGE FADER: All right. Mary, where are you? I have to be nice to her because when I'm in a nursing home in pain I don't want any problems with her.

MS. JOHNSON-ROCHE: We don't regulate nursing homes so you will be fine. I guess I'm looking at the only reference that's going forth here. I think it's commendable. I think we are on the edge of something big here and I don't know -- is 2011 a reasonable projection as to when this could be implemented?

DR. FARAH: Absolutely, it is.

JUDGE FADER: In Fader's opinion, because I'm an independent voter -- I can't stand 60 percent of

what the Democrats stand for and 60 percent of what the Republicans stand for -- I say no. I have the same love for politicians that Henry Mencken had, but I may be wrong about that.

MS. JOHNSON-ROCHE: I think it's going to be incumbent upon the group here to represent to the legislature just what the gravity of this issue is with regard to pharmacy reporting. I don't know if they know that.

DR. FARAH: From what we've heard from the alliance is if we put in the grant by January, the legislation will finish in April. If the law is passed, in July they will make a decision if we get our 400,000 for the first year. The money will be available in October.

MS. JOHNSON-ROCHE: That's pretty good.

DR. FARAH: Okay. And that's as simple as that, but it's what, every other state.

MS. JOHNSON-ROCHE: Because once you start expending it, I mean, you're --

DR. FARAH: We are number one contenders to

that, as far as the competition. We are really up there.

JUDGE FADER: All right. But at the same time, I have a feeling that if anybody can bring this system home in the future, it's Bruce and David. But the question is when? And it's not going to depend upon a limitation on them. It's going to depend upon a limitation on money.

DR. FARAH: Sure. The second year, then we have another 200,000 available. And that is to improve on what we have already established the first year.

So that's $600,000 available within two years, and we are number one in the forefront. No matter what we set up, there are growing pains. There are things that have to be up and going.

I think losing out on $600,000 does not make sense to me. I think the drive is within this group to make it happen, and I cannot see any reason why we cannot put all the provisions. Because waiting three years, not only we have lost that, there is no

guarantee that these kind of funds are going to be available in the future.

Therefore, our taxpayers are going to end up footing the bill for everything. Which is in one way I was saying, forget it, Charlie. You've done a good job but it's not going to happen. Because then we are competing with other monies and other sources of how this money is going to be available. This is a phenomenal opportunity for a grant. It's very realistic. We have very good prospects. I don't think we should lose out on it.

MS. JOHNSON-ROCHE: I think we've got to try harder to get some momentum here. If there is any way you can implore the politicians to feed into this -- besides that, with the number of states that have already bought into this, I think you stand a good chance right now to get a momentum.

JUDGE FADER: Ramsay is saying that the situation is such that he feels the politicians are going to be able to come into this sooner than they are going to do anything else, because they don't have

to put any money up for it. From your standpoint, what's that mean?

MS. JOHNSON-ROCHE: I think the role we can play at DEA in pushing this with you is we need to pull together some strong numbers that show the extent of the issue; why this is of more importance now.

DR. WOLF: I think that the legislature is aware of that, quite frankly. I think it's more going to come down to a matter of whether the political will turns, as to whether it will be more of a confidentiality issue, and whether there is this data out there. Or whether it's going to come down to the fact that the political will, if you will, is on the side of protecting the innocent. I really think -- in the sense of the abuse and distribution problem.

JUDGE FADER: I don't think the confidentiality, when we get through with it, is going to be a problem.

DR. FARAH: Right. I don't think so either.

MS. KATZ: But I also wonder, even if this is effectively going to be paid for by funds, if the

legislators hear that within three years there's going to be this Health Information Exchange and that this will not dump into it --

DR. FARAH: Why are we saying that? I'm not convinced that we can't.

MR. KOZLOWSKI: I agree.

MS. KATZ: Because we were just told that it would. And we were also told -- and I've met with some of these vendors. They want to build it and own it and get paid for it year after year after year.

JUDGE FADER: And keep it.

MR. KOZLOWSKI: Exactly right.

MS. KATZ: Right. There is not reason for them to be cooperative.

JUDGE FADER: Michael?

MR. WAJDA: I just have a question. I disagree in part, and I'm with Ramsay on this. I don't see that the client server model is dead. Somewhere in this cloud there needs to be portals and places where data is captured and held. Otherwise, we wouldn't have Surescripts or exchange of information

between hospitals and all of that.

I think what may change is how we perceive our own so-called stand-alone PDM. What we may consider now is just where the data is going to come from. It either plugs into the HIE, or it comes directly from pharmacists and physicians. Prescribers. So that's what we have to look at.

I don't think the client server model is gone and there wouldn't be anything wrong, I don't think, if the department had a client server model gathering this information and making it available in realtime. At that point, it could be realtime.

MR. SHARP: Well, it isn't a question of, is the concept of the client server model dead, because it's not and it never will be. That was sort of to bring it home because we all, in our homes, who connect to the Internet, have a client server model.

The real issue is integration and software that supports that model. These stand-alone systems require an enormous amount of software to support it. It also requires a huge amount of integration

challenges for the end-points.

You have roughly 1,600 pharmacies that are going to now have to do some manual data entry, or pay a lot of programmers to take out of their pharmacy management information system to dump it to a software that can then export it in some sort of FEP, some sort of user-friendly format, to this other database.

You now have to trust that it's going to, through primarily an unsecured network, to get to some place that it's stored. So now you have a security issue.

Now, you can say we can build protections in. Of course. But now you are adding more costs. For $400,000, you won't even cover the expense of the pharmacists to implement this if you look at spreading that cost around to all the pharmacies in the state for one year.

So, I mean, it will work. And by the way, any of these models can work. It's just how much do you really want to put into it, and do you want to keep dumping a lot of money and energy into something to

make it work when you have something better that's sitting out here that you could use, with less trouble and less cost?

DR. FARAH: There are 33 states today that are running their program, millions of bits of pharmacy information, and their budgets' going from $200,000 to $900,000, depending on how sophisticated their system is. Pharmacies are dumping their information right now, as it is, because they have to.

DR. LYLES: Ramsay, if this was five years ago, in 2005, I would say you're probably okay. You are just behind that.

As a state we need to go forward in the future. The failure of EMRs is going to be the incapability of inoperable databases. If you look at GE, GE is not going to be compatible with Allscripts. They are not fighting it out. It is going to take the federal government to come in and set a standard that they are going to have to be interoperable.

DR. FARAH: Then I would suggest that we then should go to our three vendors and tell them this is

where we're going. We need a system to be set up right now. You are knowing we're going to have a three-year contact with you because it's three years to get this show on the road.

Meanwhile, we get this money. We get the program going, and we set it up in such a way that we will be able to transition, knowing up front where we are going.

JUDGE FADER: All right. Monday morning I will send an e-mail to Bruce and to David, and then the same e-mail to Ramsay.

I would hope that everyone would agree with me that this is something that there's going to be two sides presented, and we're going to just tell the legislature what the situations are and the pros and cons. And then as -- and I'm going to monitor this because I've got these two well-educated people that don't speak Highlandtown and that need to, particularly since this will probably go to Pete Hammond's committee, who is from Highlandtown.

All right. And the situation is -- and then

we'll ask everybody to build upon this and to come in and to say what they want to say, pros or con, and the statistics and everything. But this will be one of the things we'll be working on more than anything else.

MS. JOHNSON-ROCHE: Question. I guess as we've discussed -- have we gone out to speak to some of those states where they are operating at a high level efficiency and don't have the issues that we are concerned about, to see what they have in place?

JUDGE FADER: We've had Oklahoma talk to us at the convention. We've had Kentucky talk to us at the convention. They've given us handouts and things of that sort as to what their costs are.

One of the programs that was presented in Washington D.C. generated the issue of how much the costs were. The costs, because of the way they categorize everything, it's just very difficult to get a hand on it. But most of the programs are costing about a million dollars to run in these situations. The question is, who's paying for all that? We just

don't know.

MS. KATZ: The argument that I thought was very interesting is that in almost every state, if you ask for the percentage of prescribers and dispensers that are using it, even if it is compulsory to use it, it's low. It's under a third. And that's because there's never money to do education and to present the data to those two entities in such a way that it's valuable to them.

Some of them haven't any idea that it exists. So that's another issue. You know, are we creating something that is going to essentially sit on a shelf and have very minimal use?

I'm not advocating one thing or another. I learned a lot in San Diego. I have a whole -- here's San Diego. But one of the things that I also learned is that -- and this is from the one presentation where there are no slides, but I took gigantic notes -- is that you cannot empirically show the success of these programs.

JUDGE FADER: Can you show that they haven't

been successful?

MS. KATZ: Well, you can show that there's been no change. So I guess that shows that there's been no change. And I'm just bringing this back. It's -- you know, it is of concern to me.

The other thing that I really wanted to get on the table, and I don't know if this is the right time or not, is that in a few states these things are looked at as public health efforts.

And in those states there is no law enforcement access. The only way -- if a particular situation escalates up to the Secretary of Health in that state, the Secretary of Health then has the authority to transfer the information to somebody in law enforcement. So I just wanted that to be on the table as well.

MR. KOZLOWSKI: If I can make one comment. Not that we're wedded to our position, but in the research that's been done in discussions with Kentucky -- I spoke with them, as well, very early on -- and a number of the other programs that are up there.

I do not recall one of them that is realtime. So if you assume, and it would be a false assumption -- well, that's what you all want, is you want to have realtime access --

DR. WOLF: I think Hawaii is realtime.

MR. KOZLOWSKI: Possibly. I'm not aware of that. But if you are going to assume, for any reason, that $400,000 covers anything, it doesn't cover a realtime system. We're not going to get -- when I've listened for the last several months of what you're all expecting from an outcome --

And purchasing, which I do, which is systems support, for $400,000 you aren't going to get there from here, and what you are going to end up with is a stick built framework of the house that you really want, but it's not going to get finished. By the time the fundings comes to get it finished, we're going to be in another sector of operation. And that's the concern.

JUDGE FADER: And, of course, on the other side is the concern that I don't think this economy is

going to turn around to have any other money available through the state for at least another three-year period of time.

MR. KOZLOWSKI: Right. Or a W economy instead of a V.

JUDGE FADER: Yeah. Okay. So this is going to be a hard sell. When we recovered from '83, it took quite a few years with an administration that was willing to do things a little bit differently.

Now, you have an administration that's trying to put everything through the state, and increase state government, which puts it in conflict with the money you want coming about through Reagan's administration, as opposed to, we don't want to put any more money in the states. So all those things are --

MR. CLARK: Well, David, even if we went with the client server, you're still talking about a tight frame there. It might not be three years, but how long would that be?

MR. SHARP: If the decision is made to use the

stand-alone method where the data is -- the software is essentially put into a medium and sent someplace. To be fully operational, you're probably looking at -- now, you can create the facade that this thing is working. But if you move beyond that to reality, three years.

MR. CLARK: So it's a trade-off. They're equal.

JUDGE FADER: All right. Let me ask you this now. We have now reached the point of Recommendation No. 11, which is the immunity. I have to put something together on that and get it out to you, which I will next week.

What other recommendations and what other subject matters do we have to address? Here on your first sheet are all of the recommendations, which means the areas --

(Cell phone interruption.)

JUDGE FADER: -- I've added No. 11, which is the immunity. What else do we need to discuss here? They're on the first sheet. First sheet of the yellow

handout.

DR. LYLES: What about 9?

JUDGE FADER: Housing of the database? As I said in the beginning, we don't have enough time today to do all these things. I had to switch, at 11:45, to completing the regulations. And then if we have any time after that, we'll go back.

DR. FARAH: Judge, could we discuss this because I won't be able to stay too long --

JUDGE FADER: Can we just finish the recommendations now? No. 11 is immunity. Anything else?

DR. WOLF: You had a long discussion last time with regard to whether there should be a fine, whether there should be -- with regard to the data getting out.

JUDGE FADER: That is all with regard to confidentiality and security. That there's part and parcel of all that, meaning the integrity of the database system that we adopt. Plus penalties, civil and criminal. Okay. That's all part of that, which

is Recommendation No. 8.

Come on, anything else? It's impossible for me not to have forgotten things. What else? What other areas do we need to cover?

(No response.)

JUDGE FADER: Oh, come on now.

DR. FARAH: I would like us to get to the access piece.

DR. WOLF: Well, if you want to add the technical review committee as a separate piece I have it in Access, but I didn't know if you wanted me to put it in there separate.

JUDGE FADER: Technical review committee. Do we need a technical review committee, or is that going to be something with regard to the Advisory Board?

MS. KATZ: No. We need a technical group. They have to be separate. Everybody has them as a separate entity.

JUDGE FADER: Technical review committee. All right, No. 13. What else have I forgotten? Immunity is 11. 12 is technical review committee. Anything

else?

(No response.)

JUDGE FADER: What other subjects have we missed?

DR. WOLF: One of the things that came up, again, getting back to access. There were several landmines along the way that I didn't anticipate at first. One of them is whether we treat the data as medical record or not. I mean, it's integral to everything -- to everything -- as far as access and security and how it's handled.

JUDGE FADER: Now, we will put that with regard to access. Anything else?

MR. KOZLOWSKI: There's one piece I wrote Georgette on and I think she forwarded it on to you. I raised it several months ago and it didn't fly, but what the heck. Sometimes lead takes two tries.

JUDGE FADER: Is that what you sent last night?

MR. KOZLOWSKI: Yes. The long and the short is, whether we have this sitting in a silo or we have

it distributed all over, the data is the data. If you've got data, it serves multiple purposes.

One of the purposes we haven't talked about is the purpose of doing public policy. One of the things the commission has is maybe the largest database, diverse database in the county, and it's being expanded because of laws that were passed in the last two years beyond where we currently are.

That database, in the identified format, allows us to do a tremendous amount of analysis, and produce reports that help legislatures, business, generally a whole array of individuals make better informed decisions when they are dealing with a particular issue.

So, now we have this capacity to look at pharmacy. I am going to share with you my life back a number of years when I started doing this. This is old stuff. We churned it -- the term that you all didn't like to start with -- but there was a group that churned that data for two reasons. One, to produce reports. Public reporting.

And the second thing was, in churning the data, identifying outliers that you could turn around quickly and go back to the prescribing physician, or the attending physician, and say, you know, something doesn't look right here. Not from an investigative standpoint, not from a law enforcement standpoint, but there has to be someone -- there should be someone, in a reasonable system, that is looking at this to see trends that are taking place, and to identify those anomalies.

We would be losing from a public good standpoint using public money, a tremendous capacity to create a much better system overall, and we would all benefit from that.

So my point, simply, is somewhere in all the 11, 12, or if we get to 13 points --

JUDGE FADER: Let's do 13 as a separate item and you and I develop on working something.

DR. WOLF: Actually, that's what the technical review, professional review committee is all about.

DR. FARAH: That's why I wanted to bring it

up. That's what we are all about.

MS. KATZ: Really what you're talking about here is the public health value of this, and whether we should only have solicited reports or unsolicited reports.

DR. WOLF: Right. That was the big landmine.

MS. KATZ: Yeah, and it varies in every state. But most states do have a database manager, and they do provide some sort of reporting.

JUDGE FADER: Ramsay, we are going to get to that but I've got to add No. 14, which is education. We have talked about that. We have gotten off a website, and we have gotten from other people, a number of things.

There are all sorts of pamphlets that are put out that we need to show here. Each of these states has, many of them, a way too long instructional guide for the physicians, instructional guide for the pharmacists, how the system works. I have to put that as part of No. 14, which is education. So let me work that up for No. 14.

Keeping in mind that Ramsay is going to kill me if I don't let him -- the Widow Fader would not like that. But is there anything else, other than these 14?

MS. KATZ: Have we discussed the issue of compulsory usage?

JUDGE FADER: Yes, we're going to do that.

DR. COHEN: Outcome. Actually, outcome measurement.

DR. FARAH: Absolutely. This is it.

DR. COHEN: I don't see that anywhere else.

JUDGE FADER: What part and parcel? Would that be a separate recommendation?

DR. COHEN: Separate. Is it worth it, and what difference does it make? You could, from the time of enactment, take a look at ADA data and find out whether there's been an increase in referrals based upon that data. I mean, have a conscious look at what you do with this data. And that's something I can't find in many states.

DR. WOLF: You will have to look and see if

there's a chilling effect from it, too.

DR. FARAH: So far we have some of this information, and I couldn't agree with you more. I think part of the reason of mining the data is to get these unassigned reports to look at a whole number of issues.

One, there's data that's being presented that showed a 20 percent decrease in opiate prescribing across the trend of states that have had these programs.

The question is, is you have, that was indeed a 20 percent decrease because they were necessary in the first place? More accountability, more education, more responsibility in prescribing so a lot of this money is not squandered anymore and more of the people --

(Cell phone interruption.)

DR. FARAH: -- versus the other argument, hey, people are afraid of prescribing because Big Brother is watching, et cetera.

MR. FRIEDMAN: So it's popping up in the

emergency rooms.

DR. FARAH: So these are the kind of things why outcome is important.

JUDGE FADER: All right. Outcome is No. 15. I'll ask this question again. Ramsay, would you now please tell us about this handout that you prepared? Does everyone have Ramsay's handout?

DR. WOLF: Actually, I'm the one that created the handout.

JUDGE FADER: Marcia's handout, okay. Please excuse me.

DR. WOLF: As I said, we started to look at this and it seemed at first as if access is going to be a fairly easy thing to do. We ran into several landmines.

We took it from the perspective that it's to be a treatment tool. However, the legislators mandated that our charge is also to allow access for law enforcement and to have it be a law enforcement tool, in addition to just a health tool.

So we decided to break it down into how people

got access, and not so much as to what they got access to. I guess that's one of the questions that can come up is, could there be different data pulled for different people for different purposes at different times?

MR. KOZLOWSKI: Sure.

MR. SHARP: Definitely.

DR. WOLF: So we'll get into that kind of later. But, obviously, we want realtime access for the prescribers and the dispensers. We will have to have a Maryland-based thing and we'll also have to have a way of verifying eligibility from other dispensers and other practitioners from out of state.

The patient access, we decided, should really be via physician only, or alternatively if you wanted to set up some kind of an agency interaction where the patients could pay a fee and get their copy or their information. That would be a different issue.

We felt that it wasn't appropriate to put the burden on the dispensers to have to be able to provide that to the patients, since we would have a better

idea of the identity of that individual in a controlled situation.

Where we couldn't agree on was whether the patient should actually walk out the door with a copy of it, whether we should be able to print a copy of it and put it in the chart, or whether it should be in a read-only type of a thing, or if there is a way of printing it out like you can do now where it says -- you can print it, but it says, confidential, do not copy, right on it. And then have it be treated as -- like psychiatric records would be treated.

But we all agreed that the data should not be disclosable in any way, shape or form. It should not be discoverable in any way, shape or form. But that once it was in the patient's hands, obviously it was the patient's to do with whatever they wanted.

The next issue is then, of course, a designee of the prescriber and the dispenser.

MR. KOZLOWSKI: Can you stop at discoverable?

DR. WOLF: Yes.

MR. KOZLOWSKI: Okay. Because I did send a

comment in on that. When you get in the issue of discoverable, and you think about it in the sense of -- if you have committed a potentially bad act, okay, why should I be precluded, as counsel for the victim, from having discoverability to prove my case, that you, in essence, created a bad act; one that meets all the tests in that process?

Why should I be precluded from being able to defend myself in that kind of an action?

DR. WOLF: Because the data that's going to be dispensed from the system is not necessarily accurate to the degree that would be necessary.

MR. KOZLOWSKI: But you would argue that in court. I mean, that gives both sides equal chance.

DR. WOLF: But why not go back and get the original record? Put the burden on you to go back and get the original record? You know, if you're going to quote from hearsay type of a thing, why not put the burden of discovery onto getting the original document?

DR. FARAH: Which would be much more relevant,

much more accurate, and much more on point for your case. Because we don't want gray, generalized statements to taint --

MR. KOZLOWSKI: I don't disagree with you. That's a good point made, except in going back to that individual medical record.

I was just pondering this the other day, having been on that side. Do I give up the opportunity to look from up on the balcony down at the hole, and see multiple players for purposes for preparing my defense? Or am I stuck going back to the medical record, knowing only you, or someone else, not seeing the whole picture?

That was my only point. I'm not really wedded to it. I just wanted to have a sense of why you felt so strongly about that.

MS. Devaris: I also have a question about the use of the information by a health occupation board.

DR. WOLF: We'll get there. We haven't gotten down that far. We'll get there. The other issue that comes up with this is what just happened in Las Vegas.

I don't know if you saw the e-mail that I sent out?

The committee sent out letters to 14 different pharmacies, including chains, and they were pretty much milquetoast letters. A year later, a woman killed a guy on the side of the road. One was killed, one was injured.

Under some means of discovery, or whatever, the plaintiff's lawyer got ahold of the letter to the pharmacy. They found out that the pharmacies didn't put anything within their individual records, or their computer records, flagging this woman.

So for the deep pocket, now they are going after wrongful death -- after the chain owner of the pharmacy.

MS. KATZ: It's the Wall Street Journal. The front page article. I brought it in actual hard copy.

DR. WOLF: And while the judge agrees that they really don't have any legal standing, the problem is that the press has taken it so out of proportion, or has taken it to the public. Now there's actual public will in Arizona to be able to make the --

MR. KOZLOWSKI: Okay. I just wanted to ask the question because you all were, you know, pretty fixed on that. That's fine. Thank you.

DR. FARAH: You're welcome. So then the next thing that we got to was, well, what about a designee of the patient and/or the dispenser, and the question of whether they should be registered as an active user in the system. They probably individually should be registered as active users.

Point VI, you can cross out. I've been told it's not practical to find an officer with a healthcare degree. So you can go ahead and cross out VI.

But then where the other part of it comes in, is the Professional Technical Review Committee is also going to have access to the data in a variety of different ways.

What we talked about now, as far as the rest of the -- the health boards, the health occupations boards, and then --

DR. LYLES: The Professional Technical Review

Committee. Are they going to have access on an individual basis or a collective basis, or how?

DR. WOLF: I think we are going to talk about that as part of No. 12, but it's probably as a collective basis.

Then there's another level of people that should have access to the data, but in a controlled setting. And so that would be law enforcement, at all levels, in all states, and the data can't just be used against a particular patient.

They also decided if they're going to be able to do it, they're going to have to be able to search it as far as a provider, as well. Because we didn't think it would fly through the legislature if only the punitive action was against the patients.

And then it gets into the Health Occupations Board. So the idea was that, either there's a single contact person from law enforcement at a variety of levels, or that these requests come in to the technical committee, to the Professional Review Committee.

They are then provided the data, obviously not realtime but within a reasonable period of time, along with an annotation of what the data might mean.

MS. Devaris: That didn't exactly answer what I was getting at.

DR. WOLF: I'm sorry. Go ahead.

MS. Devaris: My question is -- and I was an investigator, for years, for the board.

What do you do with this? Can we not use it or disclose it as a result of an investigation, or as a result of being charged? So if we can't, then we might as well go back to using the subpoena and getting the original documents.

DR. FARAH: I think the subpoena is going to be a must because it should be an access only with active investigation. Which, to our interpretation, as we discussed last time, you have to have a subpoena.

The only difference is that by going through this committee, you are going to get a report which has some more intelligence in it, rather than a

totally --

DR. WOLF: It'll be a comprehensive report.

MS. Devaris: So by using the subpoena, then, there's not a prohibition on using that and ultimately charging a licensee?

DR. FARAH: I think if you're looking for a criminal or some major issue --

JUDGE FADER: What do the police think about this?

MR. CLARK: What's the turnaround time?

DR. WOLF: We don't know.

DR. FARAH: That was one of our concerns, that we needed a small group of people, knowledgable people in the field, who have immediate access --

That's why I wanted four or five people to quickly come in on this so this does not become a problem or an issue. That's why we felt we have to have a technical group with an adviser, a legal adviser, on that so we will not be delayed, but at the same time, give you something that is of intelligence when you get it.

Because this data that could be mined could be totally ridiculous, and you need to know that as a person -- to see, do I need to pursue this? Is this a useful tool for me or not?

MR. CLARK: We don't normally do that sort of thing. I mean, we'll get information and then if there is any kind of question about this, we will go back, or through the State's Attorney's office, and bring in people who have knowledge of the proper administration and prescription of these things.

DR. FARAH: I'm missing the point. Can you please --

JUDGE FADER: Here's the situation. Why would there be reluctance in allowing the State Police to designate one person to have access to the base, allowing the State's Attorney's association to have somebody that has access to the base, and allowing the association of county police officers and everything, to have one person who has access to the base?

That person certainly will be someone that will record everything, make sure that there is

sufficient cause to do it, and be trustworthy enough so as not to hold up police investigations.

Why would there be an objection to doing that? I suggest to you that that may be the best way to do it.

DR. WOLF: I don't think there's an objection to having a single individual in the State Police, or a single individual -- and depending on the level, maybe State Police can have two or three.

JUDGE FADER: And a single individual on the Board of Physicians. And a single individual on the Board of Pharmacy.

DR. LYLES: Let me object.

JUDGE FADER: Sorry. I cut her off.

DR. LYLES: Okay.

DR. WOLF: I think the thing is when those single individuals begin to multiply, because you are going to have so many special interest groups, or each group that wants their own person to be able to access the data, I think you're now talking again -- you know, maybe there's 300 people out there.

JUDGE FADER: I don't think there's going to be 300, but I think there's going to be 25 or 30. And I'm not so sure I see any objection to that. I'm just asking this question.

MR. MOONEY: I have an objection to it, as to the State Police. I don't believe all criminal investigations throughout the state, no matter what level -- whether you're municipal, county -- have to come through the State Police.

I like the idea of a subpoena. I have to get a subpoena to get phone records, to get bank records, to get tax records. I go to you, Judge. You tell me I can have the records --

JUDGE FADER: Sometimes.

MR. MOONEY: Right. You are the ultimate authority. That's the independent voice that says that I can have the records.

JUDGE FADER: And judges are available 24 hours a day.

MR. MOONEY: Right. And that way I'm not controlling state and local --

JUDGE FADER: Would a judge then determine whether you can have access to this database?

MR. MOONEY: And I've got to tell you why I want the information, and then you decide.

DR. FARAH: I think that's perfect because independent, objective, legitimate -- we're looking for criminal stuff. Makes perfect --

JUDGE FADER: Tim?

MR. CLARK: Yes, sir. I'm agreeing with that after John and I had discussed that.

The initial proposal that I had, which revolves around the access that -- well, general law enforcement officers have to criminal records and other sensitive information, which is generally available to police officers throughout the state. But there are very severe penalties if they violate the confidentiality and that sort of thing.

In talking to John, I think the idea of a subpoena is even better. It then allows other law enforcement officers throughout the state not to have to go through the State Police. It also speeds up the

time frame.

JUDGE FADER: Do we have a consensus then, that with regard to the police department, and with regard to the State's Attorney's, that there would be a requirement of a subpoena for access to the database?

DR. WOLF: Uh-huh. Yes.

JUDGE FADER: Does anybody have any objection to that?

DR. LYLES: No.

MR. GHANDI: What about the Boards?

DR. WOLF: We're talking about the Boards separately.

JUDGE FADER: That's the next question. Okay.

MR. MOONEY: Can I make a comment on that? If we get the data that's not changed or anything, but I like your idea of the expert that we can go to --

DR. FARAH: Exactly. Advisory.

MR. MOONEY: Because I need to get all the information so that I know it's not being changed or anything. But then I come to you, Dr. Ramsay, and

say, okay, in layman's terms, what does it mean?

DR. FARAH: The answer could be, you know what? You've got to do the rest of the investigation. I can't help you there.

JUDGE FADER: You can easily take care of that by saying that every time a subpoena is issued, that a copy of that subpoena shall be transmitted by mail, by the one who obtained it, to Ramsay's committee. That can be done too.

DR. WOLF: That's what we were looking for.

DR. FARAH: You want an advisory committee to make you more efficient, you more knowledgable, you more understanding, so you don't have a witch hunt, or a crazy wasting of resources, or a much more major problem that, at face value, you may not be able to appreciate.

DR. LYLES: But you do have that at the Board.

DR. FARAH: We're not talking about the Board now. We're talking about the individual, an individual kind of situation.

MR. MOONEY: But I'll get the information

independent of you?

DR. WOLF: No, that's not --

MR. MOONEY: Whoever is controlling the database.

JUDGE FADER: All right, Marcia. The disciplinary boards.

DR. WOLF: The disciplinary boards. I think we all agreed that the health occupation boards need to be able to access the data. The question is, what about the other boards? One of the things that came up now is the NTSB, with these pilots. Do we open it up to other investigative board regulatory actions?

JUDGE FADER: Let me just say this to you. Is there any comment on the investigatory boards? I would suggest that we limit that -- is that the investigatory boards have to designate, from time to time, in writing, to the Secretary who, on the disciplinary board, shall have access, and that individual shall be certified for access so that we do not have everybody that's on the Board of Pharmacy, or in the office, or whatever, having that access.

MS. KATZ: I think that the access issue is really -- I think in a practical sense, state policeman, or an investigator from the medical board, would be making the request to a database manager. The access would really be through that person.

JUDGE FADER: Okay. Well, somehow that has to be controlled.

DR. WOLF: With a legitimate investigation.

DR. LYLES: The physicians have an adversarial relationship with the board. We do. That's just the way it is. It's never --

JUDGE FADER: But the law says --

DR. FARAH: -- the military police.

DR. LYLES: Pardon? No, no, no. We're talking about board issues.

JUDGE FADER: Bob, Bob.

DR. LYLES: Yes?

JUDGE FADER: The law says that the boards have an investigatorial function.

DR. LYLES: Absolutely.

JUDGE FADER: So it's within that

investigatorial function -- I've been yelling at this for years, but there's nobody listening to me -- that investigatory function is going to give them the authority to investigate.

DR. LYLES: But if they investigate after subpoena, that's going to limit what they are going to do, rather than, say, fishing expeditions. And I am very concerned about the board. The Board of Physicians.

JUDGE FADER: So you would say the Board of Physicians and the -- you don't mean to tell us there's politics associated with any of these boards?

DR. LYLES: This is not Texas.

JUDGE FADER: Not Texas, okay. What the situation is, what you're saying is that you think that the boards should have to go for a subpoena and they all have subpoena power.

DR. LYLES: Absolutely.

JUDGE FADER: Any questions? Any comments on any of that?

MS. Devaris: I have a comment. If you're

talking about -- and this has been mentioned -- one person being designated from a Board --

JUDGE FADER: No, that's just the alternative. I threw that out.

MS. Devaris: Because it would not work for the board. We'd have to hire one person. We have investigators that send out their own subpoenas.

JUDGE FADER: I'm just trying to generate controversy, okay, as opposed to the individual that's opposed to the subpoena. I mean, that's my -- stir things up.

DR. WOLF: So once they have the subpoena then, they have to go to whoever the clearinghouse, or the clearing person, is to get the data, as opposed to being able to access it, online, in their office, at that minute?

JUDGE FADER: That's what we're talking about now. We've already decided --

DR. FARAH: Well, right now, at the Board of Nursing and the Board of Physicians we have trained nurse investigators that go and do the work. They go

to the site, they go to the offices, they go into your office and look at the charts.

Here, if they have a bona fide investigation, they will be able to go and get some more information that will help them narrow that field.

JUDGE FADER: And let me add something here. They can't enforce their own subpoenas. If there is a controversy over the enforcement of the subpoena, it must come to a circuit court judge.

MS. JOHNSON-ROCHE: Question. You mentioned state law enforcement access. Is that the same subpoena access to DEA?

JUDGE FADER: Yes, absolutely. It would be all state and law enforcement agencies.

MR. CLARK: This was one of the reasons that I didn't initially talk about a subpoena until John reminded me that in the state system, it has to come from a judge. The DEA has administrative subpoenas.

DR. FARAH: We do too.

JUDGE FADER: But you can't enforce them. The DEA cannot -- only a federal judge can enforce that

subpoena if there's a question about it.

DR. FARAH: We do too. The caveat here, either go through a judge and say, hey, I've got this active investigation. Can you look at this?

And I felt that one of the advantages of having this technical advisory committee is that whatever you are getting has a little bit more of a qualification to assist.

MR. CLARK: I think the idea about getting a subpoena for state and local is excellent.

JUDGE FADER: How about the Boards now? We're at the point of talking about the Boards?

MS. JOHNSON-ROCHE: Isn't an administrative subpoena sufficient to get these records?

JUDGE FADER: An administrative subpoena is sufficient, but that can't enforce the administrative -- the Board of Pharmacy can go into Fader's Pharmacy and they can say, I want these records. Fader can say, blah, blah, blah, blah. Okay?

They can't enforce their own subpoena. They then have to come to a judge to enforce that subpoena.

That's what we're talking about.

DR. WOLF: It would be up to the committee to decide whether to question the subpoena to the next level, or whether to comply.

MS. JOHNSON-ROCHE: Generally, we have not been able to use an administrative subpoena.

DR. LYLES: Look, you want this to be successful?

MS. JOHNSON-ROCHE: We've gone to a district court to get a subpoena.

DR. LYLES: We want this effort to be successful.

JUDGE FADER: Well, let me say one other thing. If a subpoena is issued administratively, and you don't obey that subpoena, the permit of that physician, the license of that pharmacist, is in jeopardy just for disobeying that.

DR. WOLF: That wouldn't hold in this case because it's not an individual physician that you are going against. It's a committee.

JUDGE FADER: Well, I mean, you've got to

decide how you want to go.

DR. FARAH: Excuse me, Marcia. The committee, in principle -- this committee's principle is under the auspices of the Department of Hygiene. We are protected under state law from being --

MS. BETHMAN: So you have one unit of DHMH going to circuit court to enforce the subpoena against another unit of DHMH?

JUDGE FADER: That would be interesting. So if the Board of Physicians, or someone, wants an administrative subpoena, they issue the administrative subpoena?

MS. BETHMAN: Yes.

JUDGE FADER: And they issue it to the database? Okay. What happens then?

DR. WOLF: Either one of two things happen. Either you give the committee, or the database -- not the database manager, but the technical people -- the ability to deny that. Or you rise everything to the level of, you said, of getting a judge-based subpoena.

JUDGE FADER: Okay. Well, you've got a

problem as far as that's concerned. And that is, the technical people are not an agency of the state that have authority to do that.

The only reason that Don can authorize the issuance of a subpoena is because he is an officer recognized by the State of Maryland to do that as the chairman of the Board of Pharmacy. Without his permission, that can't be done. There's no authority given to this committee to do that.

DR. WOLF: To deny it? There's no authority to the committee to deny it?

JUDGE FADER: There's no authority presently in the law that would allow them to deny it because they're not an officer, like Don, who has taken an oath to do so.

DR. FARAH: The only difference is that that advisory group would be so savvy in the field, and in the pitfalls of getting this massive amount of data that could have all kind of problems, that they would be able to send a qualified advisory to the people looking at it. You can't take this for granted.

JUDGE FADER: Okay. The question is --

DR. WOLF: But that takes time.

JUDGE FADER: Okay. Well, that's also a consideration here as to what you want to do. But I am telling you, when he got sworn in on the Board of Pharmacy, he had to take an oath. All right? And that oath, because of who he is, is the thing that gives him permission to request that subpoena. Okay? He has the permission to deny it or request it.

This advisory board is going to have to be given legislative authority to do that and I suggest the chances of the legislature passing that are slim and none.

DR. FARAH: It's not going to happen.

JUDGE FADER: They can have advisory power, but not absolute power.

DR. FARAH: Yeah. Analyzing non-solicited reports and tie it to a public policy that helps with grants, that helps with impact.

JUDGE FADER: So how are you going to do that?

DR. FARAH: So that's what this group would

do, so that no reports come to the general advisory board without somebody looking at it.

JUDGE FADER: Now, once again, the subpoena is issued. Once the data is obtained, it's up to the Ramsay group of three to four to five people to advise the Boards as to what they can do with that data.

DR. WOLF: But they're not beholden to that advice.

DR. FARAH: No, they are not. But at least they would know.

JUDGE FADER: Okay. You can make Don Taylor beholden to that advice. But, constitutionally, you can't make the police beholden. And I would suggest that it would be wrong to make Don beholden to that advise too, because of his authority.

MR. KOZLOWSKI: When the State Police get a subpoena, okay, who at that point is going in to look at the record? Are they being precluded from looking under the tent, which is this database?

DR. WOLF: Yes.

JUDGE FADER: They go in and they subpoena the

records, okay? And then what they subpoena they get. But, see, they are subpoenaing the records from somebody. They are subpoenaing the records from a database.

MR. KOZLOWSKI: I agree. I guess my question is narrower than that. With a subpoena, through a judge, are they being precluded from looking at, accessing, manipulating, and making decisions that the Boards, or other entities, are going to have the authority to do?

JUDGE FADER: They don't have any authority. You can't limit their authority. If you're talking about the State Police, constitutionally you can't interfere with the right of the prosecutor to act on that authority. The most you can make that prosecutor do is to suggest that she consult with this advisory board. The constitution is not going to be changed.

MR. KOZLOWSKI: No, I'm trying to defend these guys. I'm not trying to restrict them. I'm trying to expand them.

DR. FARAH: No, no. What you want to do is

the report they're getting, you want to make sure it's a valid report. You want to make sure it's correct, that the elements are there.

DR. WOLF: We're not restricting their access. Basically, you're going to give them the data.

MR. KOZLOWSKI: Where I'm lost is who is the person that's going in there, the entity that's going in there to make that determination --

DR. WOLF: We haven't talked about that yet.

MR. KOZLOWSKI: -- because I can offer to you, two eyes see data very differently.

JUDGE FADER: That's the reason for Ramsay's committee.

MR. KOZLOWSKI: Well, I just think back in time. We had an entity like that and I found Attorney General's, when it was an important case, would go, you know, my eyes are better than anybody's eyes.

JUDGE FADER: Yeah. Well, I can tell you it just like we hear the Court of Appeals judges that say, there are certain people in the Attorneys General Office that have never found a statute

unconstitutional, even if it's the most ridiculous statute in the world. We understand all that stuff.

DR. LYLES: So have we gotten to the point where if they need data from the board, the board has to get a subpoena?

MS. BETHMAN: The board issues its own subpoena.

DR. LYLES: Right.

DR. WOLF: But are we going to take it to the next step?

JUDGE FADER: And the reason the board does that is because they have legislative authority to do that. Without that legislative authority? Yes.

MS. Devaris: Okay. We're still back to the point -- we issue the subpoena. You send us the data that we've asked for. What can we do with it?

JUDGE FADER: The database sends the data.

MS. Devaris: Right, the database. Then what can we do with that? I'm back to the question, can we use it to charge a licensee with a violation based on that?

DR. WOLF: No.

DR. FARAH: No. You are using it for investigative purposes. When you get it, all it's telling you is that there is a potential here and I should continue with my investigation. You still have to do the legwork.

MS. Devaris: Well, then, it's probably not going to help us that much, is what I'm saying.

JUDGE FADER: They can use the data as part of their prosecution.

MS. Devaris: Because we know that there's a problem or we wouldn't be sending it to you to begin with.

JUDGE FADER: Don?

MR. TAYLOR: The question I have is with the boards. You issue a subpoena for information. There's a time frame. If a committee has to review that data before you get it, you've got a significant time frame. Your investigation is usually three months to three years in the making, at this point, before the subpoena has ever been issued.

Now, we're going to wait for a committee to look at that information, sift through it, and then they're going to try to tell the board whether it's --

JUDGE FADER: You're not going to be able to do that. You're going to make the advisory committee available, and you're going to hope that they consult with this advisory committee. Otherwise, you are going to interfere with a Constitution of the State of Maryland and it's not going to work.

MR. TAYLOR: My point is, the advisory committee doesn't understand all the different sections of pharmacy or nursing, to be able to give us advice on how we should look at the information.

DR. FARAH: That's why you are going to designate who you want on the committee from your institution.

DR. LYLES: Let's step back a minute here. We have drifted to the point where this bill is not going to go anywhere. If I have to go back to MedChi and say the board is going to have ultimate subpoena power, this is dead in the water.

Now, we need to move past this, to the point that you are going to at least get a subpoena from a judge.

JUDGE FADER: You mean from the database?

DR. LYLES: Absolutely.

JUDGE FADER: Well, you guys are going to have a better handle on that than I do.

DR. WOLF: Which actually gets us back to, what is the data worth? There's going to be errors within the data. We already know that. So if it's making the investigator's life easier by compiling all the data in one place, that's fine.

But the problem is, it's not original data. So I think that we need to classify, again, what is the data? Is it medical record, is it --

JUDGE FADER: Let's go back. Most of the states that have enacted a statute have said that the police and the Boards can have access to this database, pursuant to some type of an investigation. Okay?

So the rest of the states are not putting any

limit on this, other than that. And Bob says if we do that in the state of Maryland it's not going to get passed.

DR. WOLF: Right. But it's not admissible. If it's not admissible without the underlying documentation, then it's not admissible.

MS. BETHMAN: But it's used as a tool to get the underlying document.

JUDGE FADER: It can be used as a tool, correct.

DR. FARAH: That's the point. That's all it is. That's why I've said the advisory committee is good to have because you may have so much junk in there that you don't know how to interpret. At least somebody can point you --

DR. WOLF: Right. But I think the question that you're asking is, can the board act on the database data without getting the original information that was requested?

DR. FARAH: The board has to have very specific charges, on very specific issues, on very

specific -- you can't have a charge, willy-nilly, just because suspicion from a report.

JUDGE FADER: The board is not going to be able, and the State Police are not going to be able, to use the data to prosecute. They are going to have to go out and get the additional data, from the source, in order to prosecute.

MR. MOONEY: Same thing with driving records. We have to go get the original driving record.

DR. WOLF: But what about if the board were to use the data to do an emergency cease and desist?

MS. BETHMAN: No, no, no. You still need evidence. You still require evidence.

DR. FARAH: The way they do a summary suspension is based on a specific egregious situation which comes up that would call the board.

And the answer to your question, right now -- here's managed care, right now, when you have the decision making -- I mean, you're talking 24-hour turnaround. You're talking maximum 72-hour turnaround in this. That's why there has to be a small

committee. That's why it has to be experts in the field. That's why they have to be nimble.

MR. TAYLOR: By requiring experts in the field, you've expanded it from a small committee to a large committee.

JUDGE FADER: Just a second now. Just a second. That's why the committee has to be someone they don't have to go to.

MS. BETHMAN: Right.

JUDGE FADER: Okay. It's going to be a committee there for the assistance of the board, for the assistance of the State Police, but someone they don't have to go to.

DR. FARAH: But the job of the committee would be to look at unsolicited reports, make sure that that's --

DR. WOLF: But that's as controversial as it gets. So we'll get there later.

DR. FARAH: You need that for funding. You need that for value, for public health policy.

MS. Devaris: How are you going to be able to

tell if I send you a subpoena that says, I want all of the prescription records, for Suzy Q, from January 1st --

JUDGE FADER: It happens all the time.

MS. Devaris: I know. But how are they going to determine whether that's a valid investigation? You cannot put in that subpoena the purpose of the subpoena.

JUDGE FADER: Well, I get those subpoenas, okay, and when you go after medical records, and when you go after other records, there is a required notice that that be sent -- a copy of that be sent to the party whose records they are, unless I sign a waiver based upon good cause why that shouldn't be. And here's what I get.

I get telephone records or prescription records, whatever it is. It says in here that it would interfere with the investigation to disclose these records because -- and they put all those specifics in there in order to convince me not to require to send a notice.

For instance, I've gotten all sort of financial information having to do with some politicians once in a while, that they've taken money for this, they've taken money for that, that this was paid, and was that paid, and they come in with a subpoena.

Remember, the financial article says that the copy of that subpoena has to be sent to Don, okay, if he's the target. But I can waive that, as part of the process, if I determine that there are facts to support the allegation that it would interfere with the investigation. That has been going on for hundreds of years.

MS. JOHNSON-ROCHE: I just want to raise the question. Generally, when I want to say a number of us when we request this kind of information at DEA, a lot of times it has to do with public interest issues. We don't ask for this information as a fishing expedition.

To give you an example, we had a situation recently that we had a number of overdoses that

resulted in deaths of patients. In an instance like that, we are looking at a serious public interest threat. We want to see what other information is out there that could support us toward any suspension of the doctor's registration, or pharmacist registration, whatever the case may be.

I want to know, is it going to be a bureaucracy situation if we're coming in with a subpoena for records, prescription records, for instance?

DR. WOLF: For a particular individual who's deceased, or on a particular doctor?

MS. JOHNSON-ROCHE: It could be any of the above. We want to look at the pharmacy's records, we want to look at --

JUDGE FADER: Okay. Here's the way that it works in the state of Maryland now.

Every time the DEA has sat in my dining room, they have had a state officer with them. The cooperation between the law enforcement officers is that a local person, a local policeman comes with them

and the DEA are sitting there with them.

So I can't imagine there's not going to an immediate turnaround because you all cooperate with one another.

MS. JOHNSON-ROCHE: So it's requisite that a state officer --

JUDGE FADER: Well, it's only requisite that a state officer because the state officer is the one that has the authority to go and break down the doors.

MR. CLARK: That's not exactly the case here. I mean, we serve plenty of search warrants, federal search warrants and arrest warrants. It's not required.

JUDGE FADER: No, but if you come to me, as a state court judge -- then I -- they come to me and they get the authorization for and on behalf of the DEA, but the state person is there. All I'm saying is, it's never been a problem.

MR. CLARK: No. We do this all the time. It's at a federal level where these subpoenas are issued, and I've had a couple of instances where the

telephone company didn't want to respond. The federal district court judge said, you have a choice. You can go now to jail until you cooperate, or --

JUDGE FADER: Well, that's what I say to them also.

MR. CLARK: -- or you can cooperate.

JUDGE FADER: That's exactly correct.

MR. CLARK: And it was amazing how much cooperation we got.

JUDGE FADER: Well, I understand all that.

MS. JOHNSON-ROCHE: I guess what I'm asking is, if we need to get prescription monitoring records, we need to have a State Police officer present in order to obtain those records?

JUDGE FADER: Well, that depends upon how the legislation reads. I'm suggesting that the legislation read that if you are a federal officer, that you can go directly and issue a subpoena to the database.

You have authority to do that, providing that this is within a hundred miles of what the

jurisdiction of the -- whatever it is.

DR. WOLF: But, are you saying that there might not be a bona fide investigation?

MS. JOHNSON-ROCHE: No, not at all. I'm just saying if we have a situation where we have an indication there's imminent danger out there, then we are going to want to put our hands on records right away to see if there's any additional information to support it.

JUDGE FADER: All right. So here we are. We're back to the same situation again. We have the police department and DEA straightened out. Now we're talking about the boards. The boards issue a subpoena for access to the database. Okay. They get that access, if this legislation authorizes them, like that in every other state, to have access.

DR. FARAH: If there is an active, bona fide investigation.

JUDGE FADER: They have to certify that there is.

DR. FARAH: That's the bottom line.

JUDGE FADER: They have to list the facts upon which there is. Okay? But that's going to be up to Don, and that's going to be up to whoever the chair of the Board of Physicians is.

When you come to me you just can't say to me there's an active investigation. Right, Ms. Everett? You have to set the facts and circumstances there to tell me what it is, a little bit, and why it is, because I can't take a bald allegation and conclusory statement as a fact.

So is Don going to have to do that? He's supposed to. Linda, you know about the issuance of these subpoenas.

MS. BETHMAN: Right. But once the subpoena has been determined to be warranted, and it's issued, what Shirley is saying, it just comes out as, we command you to produce X records, and that's it.

JUDGE FADER: That's correct. But you don't use those records as part of the prosecutorial tool. You only use those records as part of the investigatory tools.

DR. FARAH: So that's the bottom line.

MS. BETHMAN: It's not admissible.

MS. Devaris: So, in other words, we saw they got five prescriptions filled for Oxycontin at five different pharmacies on the same day, then we could proceed to send a subpoena to those individual pharmacies, or chain drugstore, for the documentation to support it?

JUDGE FADER: That's the hard evidence. That's in the rule of evidence.

MS. Devaris: I understand --

JUDGE FADER: That has always been. Nobody is going to detract from that.

MS. Devaris: I understand that.

JUDGE FADER: That's because otherwise it's hearsay.

MR. MOONEY: Can we come back on law enforcement real quick so that I'm clear on what we decided? The subpoena is signed by the judge for due cause. It can go to the board. The law enforcement officer is going to get the raw data --

JUDGE FADER: You're going to go to the access database.

MR. MOONEY: Right. Well, whoever has control of the information. We'll get that, but then we also have the ability to go to the board and get an interpretation?

DR. FARAH: Technical advisory group.

MR. MOONEY: The advisory group.

DR. FARAH: And then say, do I have a problem with this mumbo jumbo I've got here --

MR. MOONEY: Okay.

DR. FARAH: Does this make sense or not?

MR. MOONEY: Great.

DR. FARAH: And because it's new, because it's a lot of stuff, because it's a lot of data and analysis elements, you are going to have something that is worth your time and effort. And that's what it is.

MS. EVERETT: The committee is discretionary.

DR. FARAH: This is advisory. Where I see the committee's helpful is that we have no reporting

going in as a collective group asking for stuff, for people to not look at it to make it present for unsolicited reports.

I think that is more of a value in unsolicited reports, rather than when you are doing an active investigation. That you still have to do the investigation, that you still have to do whatever you are going to do, because you are dealing mostly with criminal issues.

We already settled that there's no civil element in here. And that's where I feel there's a lot of attention of the advisory board.

DR. DAVIS: Who is choosing the members of this committee and how large is this going to be?

JUDGE FADER: That would be up to us to decide if there was a provision like this in the former bill.

DR. WOLF: Basically, the idea is to make the committee large enough, and yet have a small enough number to act, so that you can always get --

JUDGE FADER: How many did you recommend here?

DR. WOLF: I think we recommended six with

legal counsel.

JUDGE FADER: Okay. That's about all it should be. It shouldn't be any more than that.

DR. LYLES: Okay. Now, you left the anesthesiology out?

DR. WOLF: No, I didn't. Anesthesia is -- it should be in here. Addiction, pain.

DR. FARAH: It's under pain.

DR. WOLF: Right. Anesthesia should be in there as well.

DR. DAVIS: Okay. So PM&R pain be under -- it's PM&R pain, not general PM&R?

DR. WOLF: It's pain. The question is, if you are going to start having a psychiatrist and an addiction specialist, and why do you need a psychiatrist and an addiction specialist?

DR. FARAH: Because one is medicine and one is a shrink.

DR. WOLF: Well, then, you need a pain person and you need a PM&R person. It could be an anesthesia pain person --

DR. DAVIS: Okay. But the PM&R person should do pain?

DR. WOLF: Correct. Absolutely. Which is why the society is going to designate names, who that should be.

DR. DAVIS: So basically you have two pain specialist, a PM&R and anesthesia.

DR. WOLF: A pain specialist, a PM&R, an addiction medicine specialist, a psychiatrist, some type of a nurse practitioner that treats pain, and anesthesia.

DR. DAVIS: I just wanted a clarification that the PM&R person shouldn't be --

DR. WOLF: I'm sorry. And a pharmacist.

DR. DAVIS: All right. So as long as they all do pain. Okay.

DR. WOLF: The wording has to be such that these are acting clinicians in pain practice.

DR. DAVIS: Right. That was my issue with the PM&R person. Not somebody who does head trauma?

JUDGE FADER: It's getting late. Anything

else, Marcia?

DR. WOLF: I think, again, it gets back to how it is handled as far as non-discoverable and non-admissible --

JUDGE FADER: There's a provision in here that says this shall be non-discoverable and non-admissible in evidence.

DR. WOLF: Okay. Then the next question that comes up is how it's actually handled within the office.

When am I allowed to access it? Do I access it as the patient is walking in my door? After they are in the door, am I allowed to print it? Does it become part of the medical record, or does it become part of protected --

JUDGE FADER: In my humble opinion, you need to just have a provision that it's according to a bona fide patient/physician. You're going to have to be registered.

If you are on there at night looking at every patient, particularly me, on the database, then

somebody is going to pick up that you have all these inquiries, and is going to ask you why.

DR. FARAH: Right. You cannot have access if he's not your patient. Again, established patient first, then you look at it. You can't just screen -- am I going to accept this patient or not? Let me check; he's not my patient yet.

JUDGE FADER: You can't second-guess physicians on that. If that physician certifies that it's a bona fide physician/patient access, then you're going to have to take care of that as far as your own office system is concerned.

If you want to have them agree that you can access the database, to protect yourself you would do that. If you don't feel that you want to, and you want to put -- your lawyers are going to have to put together all sort of things as far as that's concerned.

MS. BETHMAN: What about the patient access though? If I'm a patient --

JUDGE FADER: That's one I did not get to.

MS. BETHMAN: But if I don't have a doctor, but I want to see if I'm on the database because I keep getting refused by doctors --

JUDGE FADER: I ran out of time to do that. That was No. 7, and I just could not find time to do that but I'll get something out to you.

DR. FARAH: I think it should be with somebody who is held accountable, but otherwise we cannot certify --

MS. BETHMAN: No, but what if they go to the technical committee? It's my record. Why shouldn't I be able to access it?

DR. FARAH: I have no problems in a bona fide way of getting --

MS. BETHMAN: I mean, I don't know if doctors want to be encumbered by other patients asking for printouts of this, that and the other.

MR. FRIEDMAN: Is the intent that all physicians who prescribe, all pharmacists who dispense, will be required to have access to the database?

MS. BETHMAN: No, not required. Dispensers have to report.

JUDGE FADER: They are being required to submit information to the database.

MR. FRIEDMAN: Okay.

JUDGE FADER: If they want to have access to the database, they have to be certified.

MR. FRIEDMAN: So if they don't submit to have access to the database, are they still held liable for the information that's in the database?

DR. FARAH: Absolutely not.

MR. FRIEDMAN: Okay.

MS. BETHMAN: That's another topic. No. 11.

DR. LYLES: We're not liable for the accuracy of the database, period.

DR. FARAH: Exactly.

MR. FRIEDMAN: Not the accuracy of the database but the fact that if I'm just -- this goes back to that article. If I'm dispensing and I continue -- but I don't know that this patient is abusing because I'm not using the database, am I

liable for that?

DR. LYLES: No, you should not be.

MS. BETHMAN: But the issue is, in that Wall Street Journal argument is, what if you get those unsolicited reports and you don't act.

MR. FRIEDMAN: Right. Right. That's different.

MS. JOHNSON-ROCHE: Does this apply to doctors who provide drug treatment? That was actually a couple of things I was working on, where if we have a patient seeking drug treatment and the doctor wants to look into a monitoring program to see what that patient's travails are --

JUDGE FADER: All right. Let me ask you this. Is it a bona fide patient/physician relationship?

DR. WOLF: When does that occur? Does that occur when the patient is in front of me, or when he gives me his Blue Cross number so that I can make sure that it's covered?

JUDGE FADER: The law has never said when.

DR. FARAH: It's when you have established a

patient/doctor relationship.

DR. WOLF: That may never happen.

JUDGE FADER: Well, just a second now. Here's the question. Marcia Wolf: how may I may help you? Doctor, I want you -- that's it. It's done, okay?

DR. DAVIS: No, but I haven't accepted you as a patient. Just because you say, Doctor, I want you to --

JUDGE FADER: No. She had said first, how can I help you?

DR. DAVIS: But that doesn't mean she's accepted him because he might say, Doctor, I have back pain and I want 50 Oxycontin because that's what my other doctor gave me. No, I don't use Oxycontin. I will not accept you as a patient.

JUDGE FADER: And she has said that there's --

DR. FARAH: I talk to them for a half hour before I say I'm going to take you on as a patient.

DR. DAVIS: Right. That's what I am saying. You can still say no.

JUDGE FADER: Then she says, no, I'm not going

to do it. So she doesn't have any access to the database.

DR. FARAH: When you say, I'll accept you as a patient, which means a half hour later when he shows up at the emergency room, you are on the string.

MR. FRIEDMAN: There is some language in the law that talks about doctor/patient relationship.

JUDGE FADER: It talks about it but nobody ever defines it.

DR. WOLF: Well, right now there is the ability to search cases in part of the public domain. Am I allowed to look in that for somebody that I'm deciding whether or not I want them to become my patient?

JUDGE FADER: That's an interesting question that has never been decided. You can certainly look into that if you have decided that they are going to be your patient.

If, in fact, you are wondering whether or not you are going to take them as a patient, theoretically if you pushed it to the extreme you would have to say,

okay, I'll take you on. Then you look at the database and you say, I've changed my mind. Goodbye. Okay. One way or another you are going to be able to get around that. You can fire patients, you know.

DR. WOLF: Right.

MR. TAYLOR: I have a question just for my understanding. We said that to have access to the system you have to register. Okay. I'm a part-time pharmacist. I'm working Saturday night. It's five minutes of nine. I'm getting ready to close. A patient comes in. I'm not registered with anything, but he's got a prescription for Oxycontin.

DR. WOLF: I don't have it in stock anyway. Come back and pick it up tomorrow.

JUDGE FADER: You will have to register, because you will have to put an identification code in there or the system is never going to work.

DR. DAVIS: If the point of what we're trying to do is monitor prescription drugs, and if we're saying it's Schedule II through V, or whatever we decide, then if you prescribe those drugs, shouldn't

you be mandated to register?

If you are going to prescribe Vicodin or Percocet, then you should have to register. Because if not, that's too easy for you to get off the hook saying, Well, I'm just writing them and I didn't know that they were doctor shopping. But if you are going to write, then you have the responsibility.

JUDGE FADER: Well, I don't think that's going to sell with the legislature. Okay? I think that you are absolutely correct. I agree with you.

However, it's not going to sell because we don't have a brother's keeper statute. Now, in pharmacy we do. We have a brother's keeper statute in pharmacy. How that ever got through, Donald, I have no idea. But it says that if a pharmacist sees a fellow pharmacist, blah, blah, blah, they have to report them. But that's the only place in the law I know that there's a brother --

MS. Devaris: We have it.

JUDGE FADER: You have it there, too?

MS. BETHMAN: Physical therapists have it.

MS. Devaris: And we have it for non-nurses too.

JUDGE FADER: Well, still, in the state of Maryland you have, for the pharmacy code, the description of the pharmacists and the description of the physician, that it includes this. That doesn't necessarily mean that they have to do that.

The reason is because the legislature has been very reluctant to impose statutory or regulatory statements as to what the standard of care is.

Okay. So I don't think they are going to change their mind about that. Are you right? I think you're probably right. I think that every pharmacist should be required to monitor. They're not, unless it's a medical care patient.

God, there's so many interesting issues in life. I'm sorry I'm not going to be alive for another 40-50 years to play around with all this.

DR. LYLES: Theoretical age is 120.

JUDGE FADER: All right. I don't know about the rest of you but I think we've accomplished a lot

today. I think we've got a lot more to go. We will be in touch.

Please remember, we are going to see you on the 4th, and we are going to talk to Georgette about having a nice lunch, not just bologna.

(Whereupon, the Advisory Council meeting was concluded at 1:00 p.m.)

I, Kathleen Vetters, a Notary Public of the State of Maryland, County of Baltimore, do hereby certify the within named witness personally appeared before me at the time and place herein set out, and after having been duly sworn by me, according to law, was examined by counsel.

I further certify that the examination was recorded verbatim by me and this transcript is a true record of the proceedings.

I further certify that I am not of counsel to any of the parties, nor in any way interested in the outcome of this action.

As witness my hand and notarial seal this. 18th day of November, 2009.

_____

Kathleen Vetters, Court Reporter

NOTARY PUBLIC